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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

RICHARD PLUMMER, JOHNNY BALLINGER, TIMERY UEBBING, TERRY MARTINEZ, TABATHIA GATES, SHARON WHITE, SARA MCMILLAN, ROSILAND SPENCER, RONDA HOULE, NINA VINCENT, MICHAEL MCMILLAN, MAUREEN JACQUES, LORI SHOULDERS, LEONARD HUNTER, JIMMY WEEKS, ISABEL BUCKHOLDT, DYLAN WEST, AUDRA GUERRETTAZ, HASKELL CROFT, DAWN TRUAX, SHANNON COMPSTON, DEREK DAVIS, NORVEL DICKENS, GANA BRETT, JIMMY HENDRICK, JEFFERY HINES, BRENDA LANDIS, PATRICK MCCOY, JOHN MANCUSO, MARSHA MORRIS, ANTHONY NORMIL, PIO EMILIA, NANCY SCHREIBER, WILLIE STANBERRY JR., DOUGLAS PRESTIDGE, MARYANNE WAGNER, BYOTHA THOMAS, PATRICIA SHEPARD, ROSEMARY PENTON, NICHOLAS SCHULTZ, MARY TIMMONS, MELODIE WARD, CYNTHIA GIBSON, SHEILA GOODMAN-GILBERT, KRISTAL

Case No. CV14-0961 GW-FFMx

[Removal from the Superior Court of California, County of Los Angeles, Case No. BC528729]

DEFENDANTS MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC VERTELINK, INC., WYETH, INC., WYETH PHARMACEUTICALS INC., PFIZER INC., ALEX BOLANOS, KEVIN BRADLEY, DEBBIE PAGACH, AND MARAL AMIRI'S NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. §1441(b) (DIVERSITY)

Complaint Filed: November 26, 2013

First Amended Complaint Filed: December 18, 2013

[Filed concurrently with:
1. Civil Cover Sheet;
2. Declaration of Bill McKay
3. Declaration of Michael K. Brown;

REED, PENNY ROMERO, SHIRLEY HANEY, KAREN SAPPINGTON, LINDA THOMPSON, and SCOTT SMITH,

Plaintiffs

vs.

MEDTRONIC, INC. MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC VERTELINK, INC., WYETH INC., WYETH PHARMACEUTICALS, INC., PFIZER, INC., DR. GARY K. MICHELSON, ALEX BOLANOS, KEVIN BRADLEY, DEBBIE PAGACH, MARAL AMIRI, and DOES 1 THROUGH 100, inclusive,

Defendants.

4. Declaration of Jerri Province;
5. Declaration of Kevin C. Bradley
6. Declaration of Alex Bolanos
7. Declaration of Debbie Pagach
8. Declaration of Maral Amiri
9. Dr. Gary K. Michelson's Joinder in Notice of Removal and Consent to Removal;
10. Certification of Interested Parties;
11. Corporate Disclosure Statement; and
12. Demand for Jury Trial]

TO THE CLERK OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA:

PLEASE TAKE NOTICE THAT Defendants Medtronic, Inc., Medtronic Sofamor Danek USA, Inc. ("MSD"), Medtronic Vertelink, Inc. ("Vertelink"), Wyeth, Inc., Wyeth Pharmaceuticals Inc., Pfizer Inc.,[1] Alex Bolanos, Kevin Bradley, Debbie Pagach, and Maral Amiri (collectively, the "Medtronic Defendants") hereby remove this action from the Superior Court of the State of California, Los Angeles, to the United States District Court for the Central District of California. Removal is based on 28 U.S.C. §§ 1332, 1441 and 1446. In support of this Notice of Removal, the Medtronic Defendants state as follows:

I. THE PROCEDURAL REQUIREMENTS FOR REMOVAL ARE SATISFIED

1. On or about November 26, 2013, Plaintiffs commenced this action in the Superior Court of the State of California for the County of Los Angeles, entitled *Plummer, et al. v. Medtronic, Inc., et al.*, Case No. BC528729. Plaintiffs' Complaint was not served on the Medtronic Defendants.

2. On December 18, 2013, Plaintiffs filed their First Amended Complaint ("FAC").

3. The FAC and summons were properly served on Vertelink on January 13, 2014, when Plaintiffs served Vertelink's designated agent to accept service in California via personal service by process server.

4. Plaintiffs effectuated service on Pfizer, Inc. on January 14, 2013. An incomplete summons that failed to identify Wyeth was also served on Wyeth.

5. Pursuant to 28 U.S.C. § 1446(a), a copy of all process, pleadings, orders, and other papers served on these Defendants are attached hereto as Exhibit 1.

[1] Wyeth, Inc., Wyeth Pharmaceuticals, Inc., and Pfizer, Inc. are collectively referred to as "Wyeth" or the "Wyeth Defendants."

6. Plaintiffs improperly attempted to mail paper copies of the FAC to Medtronic, Inc. and, according to the Proof of Service attached to said mailing, defendants MSD, Alex Bolanos, Kevin Bradley, Debbie Pagach, and Maral Amiri also were mailed paper copies. However, these mailings did not effectuate proper service on any of these defendants because no summons or other papers required for service by mail were included.[2] Plaintiffs later attempted to execute personal service on Alex Bolanos and Debbie Pagach, but said service was improper because it was performed on the companies these defendants work for, and not on these defendants or their designated agents personally. Upon information and belief, the Medtronic Defendants are unaware of any attempts to personally serve Maral Amiri or Kevin Bradley with the FAC.

7. Under 28 U.S.C. § 1446(b), this Notice of Removal must be filed within 30 days of service of the Complaint and summons. Plaintiffs did not properly serve Vertelink until January 13, 2014, when they served Vertelink's designated agent to accept service in California via personal service. Vertelink's last day to remove did not begin to run until it was properly served, and since Defendants are filing this Notice on February 7, 2014, removal is timely.[3]

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[2] Under California law, a copy of the summons and complaint, two copies of the notice and acknowledgment form, and a return envelope, postage prepaid, addressed to the sender must be included for service by mail. Cal. Civ. Pr. § 415.30(a). For service on out of state corporations by mail, copies of the summons and complaint "by first-class mail, postage prepaid, requiring a return receipt" (i.e., certified or registered mail) must be used. [CCP § 415.40] Where the defendant is a corporation, the "person to be served" is one of the individuals specified by statute to be served on its behalf (CCP § 416.10(b); *see also Dill v. Berquist Const. Co., Inc.*, 24 Cal. App. 4th 1426, 1436 (1994); *Cruz v. Fagor America, Inc.* (2007) 146 Cal. App. 4th 488, 497 (2007) Thus, mailing a summons to the corporation itself is not valid service. Rather, the summons must be mailed to an individual who may be served on its behalf. *Dill*, 24 Cal. App. 4th at 1436.

[3] For purposes of removal, federal courts treat service of process in state court actions under state law, and in most states – including California – state law requires that the summons and complaint be served together. In such states, the 30–day period for removal runs only upon such service. *Murphy Bros., Inc. v. Michetti Pipe Stringing,*

8. Finally, Dr. Gary K. Michelson has consented to this Removal pursuant to the Notice of Joinder filed concurrently herewith.

9. No previous request has been made for the relief requested herein.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 84(c)(2) and 1441(a), because the United States District Court for the Central District of California is the federal judicial district embracing the Superior Court of California, County of Los Angeles where this action was originally filed.

11. Concurrent with the filing of this Notice, the Medtronic Defendants are serving this Notice on Plaintiffs' counsel and filing a copy of the Notice with the Clerk of the Superior Court of California, County of Los Angeles.

12. By filing a Notice of Removal in this matter, the Medtronic Defendants do not waive their right to object to service of process, the sufficiency of process, jurisdiction over the person, or venue, and they specifically reserve the right to assert any defenses and/or objections to which they may be entitled.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441

13. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332. Diversity jurisdiction exists where (1) the amount in controversy exceeds $75,000, exclusive of interest and costs, and (2) the suit is between citizens of different states. *Lee v. Am. Nat'l Ins. Co.*, 260 F.3d 997, 1004 (9th Cir. 2001). Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

Inc., 526 US 344, 354 (1999) (holding that delivery of a courtesy copy of a complaint, absent a summons, was not sufficient service to trigger the thirty-day removal period under 28 U.S.C. § 1446); *see also Emma Court LP v. United American Bank*, 2009 WL 4456387, *2-3 (N.D. Cal. Nov. 30, 2009) (*citing Murphy Bros.* and holding same; noting that that hand delivery of complaint to defendant's attorney where summons was not attached did not constitute proper service under California law and therefore said "service" did not trigger the 30-day deadline to remove).

A. The Amount In Controversy Requirement Is Satisfied

14. The Medtronic Defendants filed this Notice of Removal in good faith and on a reasonable basis in law and in fact that the requisite amount in controversy is being sought in this action. Where, as here, Plaintiffs fail to allege a specific amount of damages in the Complaint, the District Court must "examine the complaint to determine whether it is 'facially apparent' that the claims exceed the jurisdictional amount." *White v. FCI USA, Inc.*, 319 F.3d 672, 675 (5th Cir. 2003). When the plaintiff does not expressly seek damages in excess of the jurisdictional minimum, the defendant bears the burden of demonstrating that "it is more likely than not" that the plaintiff's claims meet the federal amount-in-controversy requirement. *Matheson v. Progressive Specialty Ins. Co.*, 319 F.3d 1089, 1090 (9th Cir. 2003); *Gafford v. Gen. Elec. Co.*, 997 F.2d 150, 158 (6th Cir. 1993) (citation omitted), *overturned on other grounds by Hertz Corp. v. Friend*, 130 S. Ct. 1181 (2010); *see also Williams v. Best Buy Co.*, 269 F.3d 1316, 1319 (11th Cir. 2001) ("When the complaint does not claim a specific amount of damages, removal from state court is proper if it is facially apparent from the complaint that the amount in controversy exceeds the jurisdictional requirement."). In determining whether the jurisdictional amount has been satisfied, the amount in controversy "is not measured by the low end of an open-ended claim, but rather by a reasonable reading of the value of the rights being litigated." *Kenneth Rothschild Trust v. Morgan Stanley Dean Witter*, 199 F. Supp. 2d 993, 1001 (C.D. Cal. 2002) (citing *Angus v. Shiley Inc.*, 989 F.2d 142, 146 (3d Cir.1993)).

15. Here, the allegations in Plaintiffs' Complaint demonstrate that the amount in controversy in this matter exceeds $75,000, exclusive of interest and costs. The Complaint asserts that each of the Plaintiffs underwent surgical procedures with the Infuse Bone Graft, and each of the fifty patients alleges numerous physical, mental, and emotional damages allegedly stemming from the use of the Infuse Bone Graft in their respective spine surgeries. *See Complaint* ¶¶ *16-63.*

16. The Complaint therefore seeks general and specific damages, economic

and non-economic damages, punitive and exemplary damages, pre-judgment and post-judgment interest, costs of the suit and any other relief the court deems just and proper. *See Prayer for Relief.*

17. Plaintiffs' allegations of injury are similar to others that have been found to satisfy the amount in controversy requirement. For example, in *Gebbia v. Wal-Mart Stores,* 233 F.3d 880, 881 (5th Cir. 2000), the Fifth Circuit found that alleged damages in a slip and fall case for "medical expenses, physical pain and suffering, mental anguish and suffering, loss of enjoyment of life, loss of wages and earning capacity, and permanent disability and disfigurement" satisfied the jurisdictional amount. *See also Luckett v. Delta Airlines, Inc.*, 171 F.3d 295, 298 (5th Cir. 1999) (finding that alleged damages to property, travel expenses, emergency ambulance trip, 6-day hospitalization, pain and suffering, humiliation, and an inability to do housework satisfied the jurisdictional amount); *Mendoza v. American Airlines, Inc.*, Case No. 10-7617 RSWL , 2010 WL 5376375, 3 (C.D. Cal. Dec. 22, 2010) (allegations of loss of income, lost benefits and the ongoing emotional and mental distress, punitive damages and attorney's fees sufficient to establish amount in controversy). It is also well established that punitive damages are included in determining the amount in controversy. *Gibson v. Chrysler Corp.*, 261 F.3d 927, 946 (9th Cir. 2001); *Hayes v. Equitable Energy Resources Co.*, 266 F.3d 560, 572 (6th Cir. 2001). Thus, the jurisdictional amount in controversy requirement under § 1332(a) is satisfied.

B. There Is Complete Diversity Of Citizenship Between All Properly Joined Parties

18. There is complete diversity between the properly joined parties to this action.[4]

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[4]As discussed more fully below, the joinder of multiple Plaintiffs from different states whose only connection to one another is that each had a surgeon who allegedly implanted an Infuse Device via an off-label procedure is improper under the Federal

19. The Complaint alleges that Plaintiff Terry Martinez is "an adult individual who at all times relevant hereto was residing in the State of California." *Complaint ¶ 16.*

20. The Complaint alleges that Plaintiff Johnny Ballinger is "an adult individual who at all times relevant hereto was residing in the State of Kentucky." *Id. ¶ 17.*

21. The Complaint alleges that Plaintiff Timery Uebbing is "an adult individual who at all times relevant hereto was residing in the State of Michigan." *Id. ¶ 18.*

22. The Complaint alleges that Plaintiff Tabathia Gates is "an adult individual who at all times relevant hereto was residing in the State of Tennessee." *Id. ¶ 19.*

23. The Complaint alleges that Plaintiff Sharon White is "an adult individual who at all times relevant hereto was residing in the State of Florida" *Id. ¶ 20.*

24. The Complaint alleges that Plaintiff Sara McMillan is "an adult individual who at all times relevant hereto was residing in the State of Ohio." *Id. ¶ 21.*

25. The Complaint alleges that Plaintiff Rosiland Spencer is "an adult individual who at all times relevant hereto was residing in the State of Alabama." *Id. ¶ 22.*

26. The Complaint alleges that Plaintiff Ronda Houle is "an adult individual who at all times relevant hereto was residing in the State of Georgia." *Id. ¶ 23.*

27. The Complaint alleges that Plaintiff Nina Vincent is "an adult individual who at all times relevant hereto was residing in the State of Alabama." *Id. ¶ 24.*

28. The Complaint alleges that Plaintiff Michael McMillan is "an adult individual who at all times relevant hereto was residing in the State of Ohio." *Id. ¶*

Rules of Civil Procedure.

25.

29. The Complaint alleges that Plaintiff Maureen Jacques is "an adult individual who at all times relevant hereto was residing in the State of Connecticut." *Id.* ¶ *26.*

30. The Complaint alleges that Plaintiff Lori Shoulders is "an adult individual who at all times relevant hereto was residing in the State of Illinois." *Id.* ¶ *27.*

31. The Complaint alleges that Plaintiff Leonard Hunter is "an adult individual who at all times relevant hereto was residing in the State of Missouri." *Id.* ¶ *28.*

32. The Complaint alleges that Plaintiff Jimmy Weeks is "an adult individual who at all times relevant hereto was residing in the State of Mississippi." *Id.* ¶ *29.*

33. The Complaint alleges that Plaintiff Isabel Buckholdt is "an adult individual who at all times relevant hereto was residing in the State of Texas." *Id.* ¶ *30.*

34. The Complaint alleges that Plaintiff Dylan West is "an adult individual who at all times relevant hereto was residing in the State of Ohio." *Id.* ¶ *31.*

35. The Complaint alleges that Plaintiff Audra Guerrettaz is "an individual who at all times relevant hereto was residing in the State of Washington." *Id.* ¶ *32.*

36. The Complaint alleges that Plaintiff Haskell Croft is "an individual who at all times relevant hereto was residing in the State of Georgia." *Id.* ¶ *33.*

37. The Complaint alleges that Plaintiff Dawn Truax is "an adult individual who at all times relevant hereto was residing in the State of Colorado." *Id.* ¶ *34.*

38. The Complaint alleges that Plaintiff Shannon Compton is "an adult individual who at all times relevant hereto was residing in the State of California." *Id.* ¶ *35.*

39. The Complaint alleges that Plaintiff Derek Davis is "an adult individual who at all times relevant hereto was residing in the State of Ohio." *Id.* ¶ *36.*

40. The Complaint alleges that Plaintiff Norvel Dickens is "an adult individual who at all times relevant hereto was residing in the State of Texas. *Id.* ¶ *37.*

41. The Complaint alleges that Plaintiff Gana Brett is "an individual who at all times relevant hereto was residing in the State of Nebraska." *Id.* ¶ *38.*

42. The Complaint alleges that Plaintiff Jimmy Hendrich is "an adult individual who at all times relevant hereto was residing in the State of Missouri." *Id.* ¶ *39.*

43. The Complaint alleges that Plaintiff Jeffery Hines is "an adult individual who at all times relevant hereto was residing in the State of Kentucky." *Id.* ¶ *40.*

44. The Complaint alleges that Plaintiff Brenda Landis is "an adult individual who at all times relevant hereto was residing in the State of Pennsylvania." *Id.* ¶ *41.*

45. The Complaint alleges that Plaintiff Patrick McCoy is "an adult individual who at all times relevant hereto was residing in the State of Texas." *Id.* ¶ *42.*

46. The Complaint alleges that Plaintiff John Mancuso is "an adult individual who at all times relevant hereto was residing in the State of New York." *Id.* ¶ *43.*

47. The Complaint alleges that Plaintiff Marsha Morris is "an adult individual who at all times relevant hereto was residing in the State of Georgia." *Id.* ¶ *44.*

48. The Complaint alleges that Plaintiff Anthony Mormil is "an adult individual who at all times relevant hereto was residing in the State of New Jersey." *Id.* ¶ *45.*

49. The Complaint alleges that Plaintiff Pio Emilia is "an adult individual who at all times relevant hereto was residing in the State of Florida." *Id.* ¶ *46.*

50. The Complaint alleges that Plaintiff Nancy Schreiber is "an adult individual who at all times relevant hereto was residing in the State of Georgia." *Id.* ¶ *47.*

51. The Complaint alleges that Plaintiff Willie Stanberry Jr. is "an adult individual who at all times relevant hereto was residing in the State of Pennsylvania." *Id.* ¶ *48.*

52. The Complaint alleges that Plaintiff Douglas Prestidge is "an adult individual who at all times relevant hereto was residing in the State of Arizona." *Id.* ¶ *49.*

53. The Complaint alleges that Plaintiff MaryAnne Wagner is "an adult individual who at all times relevant hereto was residing in the State of Illinois." *Id.* ¶ *50.*

54. The Complaint alleges that Plaintiff Byotha Thomas is "an adult individual who at all times relevant hereto was residing in the State of Ohio." *Id.* ¶ *51.*

55. The Complaint alleges that Plaintiff Patricia Shepard is "an adult individual who at all times relevant hereto was residing in the State of North Carolina." *Id.* ¶ *52.*

56. The Complaint alleges that Plaintiff Rosemary Penton is "an adult individual who at all times relevant hereto was residing in the State of Alabama." *Id.* ¶ *53.*

57. The Complaint alleges that Plaintiff Richard Plummer is "an adult individual who at all times relevant hereto was residing in the State of California." *Id.* ¶ *54.*

58. The Complaint alleges that Plaintiff Nicholas Schultz is "an adult individual who at all times relevant hereto was residing in the State of Wisconsin." *Id.* ¶ *55.*

59. The Complaint alleges that Plaintiff Mary Timmons is "an adult individual who at all times relevant hereto was residing in the State of California." *Id.* ¶ *56.*

60. The Complaint alleges that Plaintiff Melodie Ward is "an adult individual

who at all times relevant hereto was residing in the State of Wisconsin." *Id.* ¶ *57.*

61. The Complaint alleges that Plaintiff Cynthia Gibson is "an adult individual who at all times relevant hereto was residing in the State of Tennessee." *Id.* ¶ *58.*

62. The Complaint alleges that Plaintiff Sheila Goodman-Gilbert is "an adult individual who at all times relevant hereto was residing in the State of Oklahoma." *Id.* ¶ *59.*

63. The Complaint alleges that Plaintiff Kristal Reed is "an adult individual who at all times relevant hereto was residing in the State of Alabama." *Id.* ¶ *60.*

64. The Complaint alleges that Plaintiff Penny Romero is "an adult individual who at all times relevant hereto was residing in the State of California." *Id.* ¶ *61.*

65. The Complaint alleges that Plaintiff Shirley Haney is "an adult individual who at all times relevant hereto was residing in the State of Texas." *Id.* ¶ *62.*

66. The Complaint alleges that Plaintiff Karen Sappington is "an adult individual who at all times relevant hereto was residing in the State of Illinois." *Id.* ¶ *63.*

67. The Complaint alleges that Plaintiff Linda Thompson is "an adult individual who at all times relevant hereto was residing in the State of Louisiana." *Id.* ¶ *64.*

68. The Complaint alleges that Plaintiff Scott Smith is "an individual who at all times relevant hereto was residing in the State of Florida." *Id.* ¶ *65.*

69. As Plaintiffs allege (*Id.* ¶ *66*), Defendant Medtronic, Inc. is a Minnesota corporation which has its principal place of business in Minneapolis, Minnesota. *See* 28 U.S.C. § 1332(c)(1); *see also Declaration of Jerri Province ("Province Decl."),* ¶ *4; Branson v. Medtronic, Inc.*, No. 5:06-cv-332-Oc-10GRJ, 2007 WL 170094, at *4 (M.D. Fla. Jan. 18, 2007) (denying plaintiff's motion to remand following removal by Medtronic on the ground that Medtronic's principal place of business is in

Minnesota). Thus, Medtronic is a citizen of Minnesota. *See* 28 U.S.C. § 1332(c)(1).

70. Plaintiffs also allege (*Complaint* ¶ *67*) that Defendant MSD is a Tennessee corporation with its principal place of business in Memphis, Tennessee. Thus, MSD is a citizen of Tennessee. *See* 28 U.S.C. § 1332(c)(1); *see also Province Decl.*, ¶ *4*.

71. Although Plaintiffs Tabathia Gates and Cynthia Gibson are also allegedly residents of Tennessee, they are not properly joined under Federal Rule of Civil Procedure Rule 20, because they have no connection whatsoever with the other Plaintiffs, and their joinder in this action is an attempt to prevent the Medtronic Defendants from rightfully removing this case. Moreover, Plaintiff Cynthia Gibson's claims must fail because her alleged implant took place on either June 12, 2002 or January 8, 2003, both dates that fall outside Tennessee's Statute of Repose, which requires that all product liability actions "must be brought within ten (10) years from the date on which the product was first purchased for use or consumption, or within one (1) year after the expiration date of the anticipated life of the product, whichever is the shorter." *See* Tenn. Code Ann Section 29-28-103; *see also Wahl v. General Electric Company*, 2013 U.S. Dist. LEXIS 162320 at *19 (M.D. Tenn. Nov. 14, 2013). Thus this Court should dismiss the claims of Cynthia Gibson with prejudice, sever the claims of Tabathia Gates, and remand her claims to state court.

72. Defendants Wyeth, Inc., Wyeth Pharmaceuticals, Inc., and Pfizer, Inc. (collectively, "Wyeth") are all named as defendants in this action with incorporation and principal places of business in New Jersey, Pennsylvania, and New York, respectively. (*See Complaint,* ¶¶ *70-72*). Thus, these three entities are citizens of New Jersey, Pennsylvania, and New York, respectively.

73. Although Plaintiff Anthony Mormil is allegedly a resident of New Jersey, Plaintiff John Mancuso is allegedly a resident of New York, and Plaintiffs Brenda Landis and Willie Stanberry Jr. are allegedly residents of Pennsylvania, they are not properly joined under Federal Rule of Civil Procedure Rule 20, because they have no

connection whatsoever with the other Plaintiffs, and their joinder in this action is an attempt to prevent the Medtronic Defendants from rightfully removing this case. Thus this Court should sever the claims of Anthony Mormil, John Mancuso, Brenda Landis, and Willie Stanberry Jr. and remand their claims to state court.

74. Vertelink is also a named defendant in this action (*Complaint, ¶ 68*), but as discussed below, Plaintiffs fail to allege facts specific to Vertelink's involvement in the claims at issue beyond (incorrectly) lumping Vertelink in with the other Medtronic entities named in the FAC. (*See FAC ¶ 69*) Plaintiffs allege that Vertelink is a California corporation (*see id. at ¶ 66*), but as discussed below, the citizenship of Vertelink must be ignored for purposes of establishing diversity.

75. Dr. Gary K. Michelson ("Dr. Michelson") is a named defendant in this action (*Complaint* ¶¶ 1, 23, 24, 73), yet as discussed below, Plaintiffs fail to allege facts specific to Dr. Michelson's involvement in the claims at issue, beyond boilerplate (and incorrect) allegations that Dr. Michelson "was partially responsible for inventing, designing, promoting, and marketing Medtronic's LT-Cage component of INFUSE." *Id.* at¶ 73. Plaintiffs also allege that Dr. Michelson "is, and at all times herein mentioned was a resident of the county of Los Angeles in the state of California." *Id.* As discussed below, the citizenship of Dr. Michelson must be ignored for purposes of establishing diversity.

76. Defendants Maral Amiri, Alex Bolanos, Kevin Bradley, and Debbie Pagach are all named as defendants in this action and are alleged to be citizens of the State of California. (*FAC,* ¶¶ 75-78). Plaintiffs allege these defendants were responsible for promoting "Infuse Bone Graft to various healthcare providers in the State of California, and other states, including those healthcare providers who were involved in the Plaintiffs' surgeries." As discussed below, the citizenship of these defendants must be ignored for purposes of establishing diversity.

77. Plaintiffs Terry Martinez, Shannon Compton, Richard Plummer, Mary Timmons, and Penny Romero are all alleged to be residents of the State of California.

(*See FAC*, ¶¶ 16, 35, 54, 56, 61) Based on the allegations contained in the FAC, these Plaintiffs implant surgeries took place in San Jose, California, San Luis Obispo, California, Santa Barbara, California, Whittier, California, San Bernardino, California, or a surrounding community of those cities. (*See FAC*, ¶¶ 16, 35, 54, 56, 61; *see also Brown Decl.*, ¶ *2*). Although these plaintiffs are allegedly residents of California, they are not properly joined under Federal Rule of Civil Procedure Rule 20, because they have no connection whatsoever with the other Plaintiffs, and their joinder in this action is an attempt to prevent the Medtronic Defendants from rightfully removing this case. Thus this Court should sever the claims of Terry Martinez, Shannon Compton, Richard Plummer, Mary Timmons, and Penny Romero and remand their claims to state court.

78. Finally, upon information and belief, none of the remaining DOE defendants have been substituted with any named defendants or been served with process in the state court action. For purposes of removal, "the citizenship of defendants sued under fictitious names shall be disregarded." 28 U.S.C. § 1441(a); *accord Soliman v. Phillip Morris Inc.*, 311 F.3d 966, 971 (9th Cir. 2002); *McCabe*, 811 F.2d at 1339. Therefore, the citizenship of DOES 1 through 100 should be disregarded for purposes of diversity

79. Complete diversity exists among the properly joined parties, and no defendant that is a citizen of the State of California has been properly joined and served to this action. 28 U.S.C. § 1441(b)(2). Removal based on the diversity of citizenship is therefore proper.

C. California Defendants Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach Are Fraudulently Joined

80. As the Ninth Circuit has explained, "[f]raudulent joinder is a term of art." *McCabe*, 811 F.2d at 1339. A defendant is fraudulently joined and its presence in the lawsuit is ignored for purposes of determining diversity "[i]f the plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to

the settled rules of the state." *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001); *citing McCabe*, 811 F.2d at 1339. Further, the defendant "is entitled to present the facts showing the joinder to be fraudulent." *Id.* To that end, courts may consider the allegations in the complaint and the facts presented by the defendant in its notice of removal, including affidavits or other evidence on the issue of whether a particular defendant's joinder is fraudulent. *See Ritchey,* 139 F.3d at 1318; *West America Corp. v. Vaughan-Bassett Furniture Co., Inc.*, 765 F.2d 932, 936 n. 6 (9th Cir. 1985).

81. As set forth below, the FAC fails to allege any facts sufficient to impose any liability on Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach. The FAC, instead, makes clear that this is a product liability action, and by Plaintiffs' own allegations (or the lack thereof), Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach are fraudulently joined. Moreover, the analysis of the facts and applicable legal authority confirms that there is no basis for Plaintiffs' claims against Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach.

(a) Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach Are Fraudulently Joined and Their Presence Should Be Ignored for Purposes of Establishing Diversity

82. Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach are fraudulently joined and their citizenship must be ignored for the purpose of establishing diversity. *Burns, et al., v. Medtronic, Inc. et al.*, 2013 WL 5596122, *1-2 (C.D. Cal. Oct. 8, 2013) (Infuse Device in which the Court found Dr. Michelson fraudulently joined based on similar allegations as here); *Dawson v. Medtronic,* 2013 WL 3322040, *1-2 (C.D. Cal. Mar. 8, 2013) (granting Medtronic's Motion to Transfer Venue and noting that Vertelink "is not in any way connected to the Infuse Device at issue" and that plaintiff fails to allege any facts connecting Vertelink or the patent it holds for an expandable fusion cage to the Infuse Device); *Blankenship v. Medtronic*, 2013 WL 332031, *3 (C.D. Cal. June 7, 2013) (referencing *Dawson* and holding same); *see also McCabe*, 811 F.2d at 1339; *accord Ritchey*, 139 F.3d at 1318 ("It is a

commonplace that fraudulently joined defendants will not defeat removal on diversity grounds.") (citations omitted); *United Computer Sys.*, 298 F.3d at 762 (A defendant's presence in the lawsuit is ignored for purposes of determining diversity where there is an obvious failure to state a cause of action against the resident defendant.).

(b) Plaintiffs' Fail to Plead Sufficient Facts to Meet Their Initial Pleading Burden Under *Twombly* Regarding Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach

83. The United States Supreme Court has made clear that when filing a complaint, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic v. Twombly*, 127 S.Ct. 1995, 1964-65, 550 U.S. 544, 167 L.Ed.2d 929 (2007); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 77 U.S.L.W. 4387, 173 L.Ed.2d 868 (2009) (holding that "threadbare recitals of a cause of action's elements supported by mere conclusory statements" is insufficient and extending *Twombly*'s holding to contexts outside of anti-trust).

84. Here, Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach are fraudulently joined because Plaintiffs have failed to make any material allegations against them. *See, e.g., Brown v. Allstate Insur.,* 17 F. Supp. 2d 1134, 1137, (S.D. Cal. 1998) (finding in-state defendants fraudulently joined where "no material allegations against [the in-state defendants] are made"). In fact, as one court held, there is "no better admission of fraudulent joinder of [the resident defendants]" than the failure of the plaintiff "to set forth any specific factual allegations" against them. *Lyons v. American Tobacco Co.*, No. Civ. A. 96-0881-BH-S, 1997 WL 809677, at *5 (S.D. Ala. Sept. 30, 1997). Plaintiffs must provide some factual allegations of the grounds upon which the claims rest (*Twombly*, 127 S.Ct. at 1965 n.3), and their failure to assert material factual allegations against Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach is a hallmark of fraudulent joinder. *See, e.g. Results Mktg., Inc. v. Buffalo-Lake Erie Wireless Sys. Co.*, LLC, 2008 WL 209865, No. 3:CV-08-0382,

*2 (M.D. Pa. May 16, 2008) (citing *Twombly* and finding no plausible basis for cause of action against non-diverse defendants); *Tippen v. Republic Fire & Casualty Ins. Co.*, 2007 WL 5219352, Nos. 06-07701, 06-8440, *2 (E.D. La. Nov. 28, 2007) (citing *Twombly* relating to standard of pleading and noting that in analyzing the propriety of removal, the court may pierce the pleadings); *Taylor w. Shelter Lincoln Mercury Ltd.*, 2007 WL 3244701, No. 2:07-CV-0097, *1-2 (W.D. La. Nov. 2, 2007) (citing *Twombly* and finding fraudulent joinder); *Pascale Serv. Corp. v. Int'l Truck and Engine Corp.*, 2007 WL 809677, Nos. 07-0247-S, *2-4 (D.R.I. Oct. 1, 2007) (citing *Twombly* and finding fraudulent joinder).

85. Plaintiffs fail to allege any facts showing that Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach had anything to do with the Infuse Device Plaintiffs allegedly received. Moreover, the reality is that no set of facts will establish Vertelink or Dr. Michelson's involvement with the Infuse Device because neither Vertelink nor Dr. Michelson had any involvement with the creation, design, promotion or marketing of the Infuse Device. *See Declaration of Bill McKay ("McKay Decl."), ¶ 4; Province Decl., ¶ 5; see also Carmela Vitale et al. v. Medtronic, Inc. et al.*, No. BC524044 (Cal. Super. Ct. Jan. 21, 2014) (plaintiffs' voluntary dismissal of Dr. Michelson as a party in a case where he was named as a defendant with similar allegations involving the Infuse Device) (attached to *Brown Decl.* as Exhibit A; *see also Brown Decl.*, Exhibit B, which contains excerpts from the Complaint in the *Vitale* matter that correspond to the allegations made against Dr. Michelson in Plaintiffs' FAC here); *Burns,* 2013 WL 5596122 at *1-2 (in an Infuse Device case where Dr. Michelson was named as a defendant with similar allegations, the Court found that Plaintiffs allegations and subsequent evidence submitted in support of their Motion to Remand did not establish a connection between Dr. Michelson and the Infuse Device and he was therefore fraudulently joined); *Wright v. Medtronic, Inc.*, No. 2:13-CV-02130, at p. 3 (C.D. Cal. June 24, 2013) (in an Infuse Device case where Dr. Michelson was named as a defendant, the Court held that the

Plaintiff failed "to establish that Dr. Michelson is meaningfully connected to th[e] case") (attached to the *Brown Decl.* as Exhibit C); *Dawson*, 2013 WL 3322040 at *1-2 (C.D. Cal. Mar. 8, 2013) (granting Medtronic's Motion to Transfer Venue in an Infuse Device case and noting that Vertelink "is not in any way connected to the Infuse Device at issue" and that plaintiff fails to allege any facts connecting Vertelink or the patent it holds for an expandable fusion cage to to the Infuse Device); *Blankenship v. Medtronic*, 2013 WL 332031, *3 (C.D. Cal. June 7, 2013) (referencing *Dawson* and holding same in an Infuse Device case). Moreover, Vertelink and Dr. Michelson have ***never*** had involvement with the manufacturing, distribution processes, or promotional activities for the Infuse Device. *McKay Decl. ¶ 4; Province Decl. ¶5.*

86. Meanwhile, Amiri, Bolanos, Bradley, and Pagach had no involvement with the off-label sale or marketing of the Infuse Device that went into any of the Plaintiffs. *See Amiri Decl, ¶ 2; Bolanos Decl., ¶ 2; Bradley Decl., ¶ 2-3; Pagach Decl., ¶ 2-3.* Amiri and Bolanos were part of Medtronic's Kyphon division, and were not responsible for the sale or marketing of the Infuse Device in any capacity, as neither marketed or sold the Infuse Device. *See Amiri Decl, ¶ 2; Bolanos Decl., ¶ 2.* Meanwhile, not only did Pagach and Bradley have no involvement with the off-label sale or marketing of the Infuse Device that went into any of the Plaintiffs (*see Bradley Decl., ¶ 2-3; Pagach Decl., ¶ 2-3*), neither Bradley nor Pagach had worked in or had any oversight for sales representatives who worked in Alabama, Arizona, Colorado, Connecticut, Florida, Georgia, Illinois, Kentucky, Michigan, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, Washington, and Wisconsin during the time each Plaintiff's Infuse Device surgery allegedly took place. *See Bradley Decl., ¶ 3; Pagach Decl., ¶ 3).*

87. Indeed, in *Burns*, Judge Wilson denied the plaintiffs' Motion to Remand where the plaintiffs had asserted similar allegations as to Dr. Michelson holding that Dr. Michelson was fraudulently joined. *Burns*, 2013 WL 5596122 at *1-2.

88. Similarly, in *Wright*, Judge Wu gave that plaintiff the opportunity to

present evidence to justify her claims against Dr. Michelson, but—similar to the allegations here—the plaintiff's offer of proof merely contained a few copies of websites on which Dr. Michelson's contributions were noted and evidence of a patent dispute. *Wright*, p. 3. Judge Wu expressly found that the documents did not demonstrate that Dr. Michelson controlled the manufacturing and distribution processes for the Infuse Device or that he promoted an "off-label" use of that device to any doctors or patients. *Id.* Plaintiffs' allegations here similarly fail to connect Dr. Michelson to their claims or their alleged injuries.

89. Meanwhile in both *Dawson* and *Blankenship*, the plaintiffs opposed Medtronic's Motions to Transfer Venue to the appropriate federal district courts where the plaintiffs should have brought their claims by arguing that their preferences to bring their claims in federal court here should be given weight because Vertelink was a California corporation. Both courts rejected this argument, noting that at best, Vertelink holds a patent on a medical device called the "expandable fusion cage" and that the plaintiffs – much like the Plaintiffs here – failed to show, let alone allege, that this device had been used with the Infuse Device in spinal surgeries. *See Dawson*, 2013 WL 3322040 at *2; *Blankenship*, 2013 WL 332031 at *3. Moreover, like the Plaintiffs here, the plaintiffs in *Dawson* and *Blankenship* failed to mention the Vertelink device in their complaints, failed to allege that it was actually used in their surgery, and failed to provide any evidence to support their arguments about its use with the Infuse Device. *See Dawson*, 2013 WL 3322040 at *2; *Blankenship*, 2013 WL 332031 at *3.

90. The Complaint is simply devoid of any factual allegations linking Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach to Plaintiffs' claims or alleged injuries and the boilerplate allegations Plaintiffs do make are factually incorrect.

91. For example, Plaintiffs only specifically reference Vertelink in only a handful of paragraphs of the FAC. Paragraph 68 states that Vertelink is a California

corporation, and Paragraph 69 merely lumps it in with Medtronic, Inc. and MSD to incorrectly allege it was in the business of designing, manufacturing, constructing, assembling, inspecting, and selling the Infuse Device. Those are the only two spots where Vertelink is even mentioned in the FAC, which is not surprising: Vertelink is in no way responsible for designing, manufacturing, constructing, assembling, inspecting, or selling the Infuse Device. *See Province Decl., 5.* Vertelink does not even have any employees in the State of California. *Id.*

92. Meanwhile, Plaintiffs only specifically reference Dr. Michelson in only a handful of paragraphs of the 383 paragraph FAC. Paragraph 2 of the FAC contains the boilerplate (and incorrect) allegation that the Infuse® Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("Infuse Device") was promoted, invented, marketed, and designed in part by Dr. Michelson, while Paragraph 3 states that the LT-Cage component of the Infuse Device was "invented, in part, by Dr. Michelson. Paragraph 73 and 82 state the allegation that Dr. Michelson resides in Los Angeles, California. Finally, Paragraph 282 alleges that Dr. Michelson "substantially contributed to the development of the technology related to INFUSE," and that "Dr. Michelson has numerous patents which involved the use of cages and spinal fusion implants, which are the core of Medtronic's business."

93. Thus, other than generally lumping Dr. Michelson together with Medtronic and MSD as Defendants for purposes of their pleading, nowhere in the Complaint do they identify any specific actions taken by Dr. Michelson that would implicate him in the design, manufacture, construction, assembly, sale and/or distribution of the Infuse Device at issue in this case. Indeed, the closest Plaintiffs come is to merely allege that Dr. Michelson purportedly invented technology related in an unspecified way to the Infuse Device and holds patents on other spinal implants not specifically tied to the Infuse Device. Similar allegations were rejected by Judge Wilson in *Burns* and Judge Wu in *Wright*. *See Burns,* 2013 WL 5596122 at *1-2; *Wright*, p. 3.

94. Lastly, the allegations against Amiri, Bolanos, Bradley, and Pagach are even further removed from reality. The FAC alleges that these individuals "intentionally and/or recklessly engage in vigorous and unlawful overpromotion of the off-label use of Infuse in California, and other states," specifically alleging that "[c]ritical here is that Amiri, Bolanos, Bradley, and Pagach paid "certain orthopedic surgeons in California, including, but not limited to Drs. Jeffrey E. Deckey, David Lee Skaggs, Todd Lanman, Theodore G. Obenchain, and certain physicians at the San Francisco Spine Institute" in order to obtain testimonials and support for the off-label use of Infuse" such that they caused "the introduction [of the Infuse Device] into the stream of commerce." *See FAC*, ¶¶ 279-281. However, Amiri, Bolanos, Bradley, and Pagach have ***never*** participated in the off-label promotion of the Infuse Device or directed others to conduct off-label promotion of the Infuse Device. *See Amiri Decl, ¶ 2-33; Bolanos Decl., ¶ 2-3; Bradley Decl., ¶ 2; Pagach Decl., ¶ 2.* Amiri and Bolanos were part of Medtronic's Kyphon division, and were not responsible for the sale or marketing of the Infuse Device in any capacity, as neither marketed or sold the Infuse Device. *See Amiri Decl, ¶ 2; Bolanos Decl., ¶ 2.* Meanwhile, not only did Pagach and Bradley have no involvement with the off-label sale or marketing of the Infuse Device that went into any of the Plaintiffs (*see Bradley Decl., ¶ 2-3; Pagach Decl., ¶ 2-3*), neither Bradley nor Pagach had worked in or had any oversight for sales representatives who worked in Alabama, Arizona, Colorado, Connecticut, Florida, Georgia, Illinois, Kentucky, Michigan, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, Washington, and Wisconsin during the time each Plaintiff's Infuse Device surgery allegedly took place. *See Bradley Decl., ¶ 3; Pagach Decl., ¶ 3).* Lastly, the FAC is devoid of any facts in any of the fifty paragraphs detailing the Plaintiffs' surgeries that Amiri, Bolanos, Bradley, or Pagach ever sold or promoted the Infuse Device to any Plaintiffs' doctor or physician to substantiate the allegation that they "in part" caused "the introduction into the stream of commerce, the INFUSE product received by

Plaintiffs." *FAC*, ¶ 281; *see also id.* at 79 (alleging that Amiri, Bolanos, Bradley, and Pagach actively promoted the Infuse Device to various healthcare providers "including those healthcare providers who were involved in the Plaintiffs' surgeries.")

95. The lack of any correct material factual allegations beyond establishing Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach's California citizenship compels the conclusion that Plaintiffs fraudulently joined these parties in an attempt to defeat diversity jurisdiction. *See, e.g., Lyons,* 1997 WL 809677, at *5.

96. Simply lumping Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach in with Medtronic and MSD fails to state facts sufficient to find any basis for their participation in this case. *See, e.g., Brown,* 17 F. Supp. 2d at 1137; *Lyons,* 1997 WL 809677 at *5. And, as other courts have held, Plaintiffs cannot cure this deficiency by simply relying on allegations directed generally toward "Defendants" alone. *See In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 2002 WL 34418423 at *4-5 (W.D. Wash. Nov. 27, 2002) (allegations directed toward "defendants" or "all defendants" insufficient). Such general and conclusory allegations cannot be used to thwart removal. *Roe v. General American Life Ins. Co.*, 712 F.2d 450, 452 n. * (10th Cir. 1983) ("the joinder of a resident defendant against whom no cause of action is pleaded, or against whom there is no cause of action, will not defeat removal"); *Anderson v. Ford Motor Co.*, 303 F. Supp. 2d 1253, 1258 (W.D. Okla. 2004) ("federal courts must vigilantly protect a defendant's right to proceed in federal court against abuses and manipulations by the plaintiff," thus a defendant's right to remove cannot be defeated by the fraudulent joinder of a resident defendant).

97. Given Plaintiffs' conclusory and blatantly false allegations, it is evident that Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach have been fraudulently joined in this action. Where a non-diverse defendant has been fraudulently joined, its presence does not preclude removal. *United Computer Systems, Inc.*, 298 F.3d at 762; *Simpson*, 282 F. Supp. 2d at 1155. As such, Vertelink, Dr. Michelson, Amiri, Bolanos, Bradley, and Pagach's inclusion in this lawsuit should

be disregarded for purposes of diversity.

98. Under California law, only "manufacturers, retailers, and others in the marketing chain of a product are strictly liable in tort for personal injuries caused by a defective product." *Taylor v. Elliott Turbomachinery Co., Inc.*, 171 Cal. App. 4th 564, 575 (2009); *citing Peterson v. Superior Court*, 10 Cal. 4th 1185, 1188 (1995). The rules of products liability "focus responsibility for defects, whether negligently or nonnegligently caused, ***on the manufacturer of the completed product.***" *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 478–479 (2001) (emphasis added). As the California Supreme Court explained three decades ago, the basis for imposing liability on a particular defendant is that "he has marketed or distributed a defective product." *Taylor*, 171 Cal. App. 4th at 575; *citing Daly v. General Motors Corp.*, 20 Cal. 3d 725, 739 (1978).

99. Vertelink, Dr. Michelson Amiri, Bolanos, Bradley, and Pagach therefore have been fraudulently joined because they have absolutely no involvement of any kind with the Infuse Device at issue in this case. As such, Plaintiffs fail to allege – and, indeed, will never be able to show – that Vertelink, Dr. Michelson Amiri, Bolanos, Bradley, or Pagach was or is involved in any way with the Infuse Devices implanted in Plaintiffs such that their presence in this lawsuit is valid under any legal theory or cause of action.

D. California Plaintiffs Terry Martinez, Shannon Compton, Richard Plummer, Mary Timmons, and Penny Romero, Tennessee Plaintiffs Tabathia Gates and Cynthia Gibson, New Jersey Plaintiff Anthony Mormil, New York Plaintiff John Mancuso, And Pennsylvania Plaintiffs Brenda Landis and Willie Stanberry Jr. Are Fraudulently Misjoined

(a) The Numerous Plaintiffs' Claims Are Legally And Factually Distinct, And These Plaintiffs Are Fraudulently Misjoined

100. The doctrine of fraudulent misjoinder permits the Court to ignore the citizenship of non-diverse plaintiffs who fail to make "at least one claim that arises out of the same transaction or occurrence or series of transactions or occurrences as the other plaintiffs." *In re Rezulin Prod. Liab. Litig.*, 2002 WL 31496228, at *1

(S.D.N.Y. Nov. 7, 2002); *see also In re Diet Drugs Prod. Liab. Litig.*, 294 F. Supp. 2d 667, 673 (E.D. Pa. 2003) ("Even if a non-diverse plaintiff may have a valid cause of action against a defendant, that plaintiff may not prevent removal based on diversity of citizenship if there is no reasonable basis for the joinder of that non-diverse plaintiff with the other plaintiffs").

101. In the context of pharmaceutical and medical device product liability litigation, "the joinder of plaintiffs who have no connection to each other except the fact that they ingested [the same product] constitutes misjoinder." *In re Rezulin*, 2002 WL 31496228, at *1; *see also In re Fosamax Prods. Liab. Litig.*, 2012 WL 1118780, at *4 (D.N.J. Apr. 3, 2012) ("[G]iven the complicated causation questions that pervade drug product liability claims, Plaintiffs' claims will require divergent questions of law and fact. Accordingly, the Court finds that Plaintiffs' claims are misjoined."); *see also Baker v. Merck & Co., Inc.*, 2005 WL 5517236, *3 (D. Nev. Sept. 13, 2005) (finding misjoinder and severing and remanding claims of the non-diverse plaintiffs); *In re Diet Drugs*, 294 F. Supp. 2d at 679 (finding misjoinder and severing claims where "plaintiffs reside[d] in various states throughout the country, and were prescribed different drugs by different doctors at different times"); *Alday v. Organon USA, Inc.*, 2009 WL 3531802 at *1 (E.D.Mo. Oct 27, 2009) ("Each Plaintiff was injured at different times in different states allegedly from their use of NuvaRing that was presumably prescribed by different healthcare providers. Nor are Plaintiffs' injuries all the same. As a result, the joinder of the claims of the non-Missouri resident Plaintiffs with the claims of the Missouri resident Plaintiff was a misjoinder of parties in this suit."); *In re Prempro Prods. Liab. Litig.*, 417 F.Supp.2d 1058, 1060 (E.D. Ark. 2006) (dismissing misjoined plaintiffs where their only connection to the case is the use of a product, but where all other facts relevant to their claims are different; "Plaintiffs are residents of different states and were prescribed different HRT drugs, from different doctors, for different lengths of time, in different amounts, and suffered different injuries.").

102. As explained in more detail below, Plaintiffs' claims in this action are essentially fifty distinct product liability actions, consisting of individuals from two dozen different states, filed under a single caption. Except for the allegation that each allegedly was implanted with the Infuse Device in an off-label manner, Plaintiffs assert no other relationship to one another. Accordingly, Plaintiffs' claims are misjoined, and California Plaintiffs Terry Martinez, Shannon Compton, Richard Plummer, Mary Timmons, and Penny Romero, Tennessee Plaintiffs Tabathia Gates and Cynthia Gibson, New Jersey Plaintiff Anthony Mormil, New York Plaintiff John Mancuso, And Pennsylvania Plaintiffs Brenda Landis and Willie Stanberry Jr.'s (collectively, the "Misjoined Plaintiffs") claims should be severed.

(b) The Misjoined Plaintiffs' Claims Should Be Severed And Remanded To State Court

103. Pursuant to Federal Rules of Civil Procedure 20 and 21, permissive joinder is not an absolute right, and a court has broad discretion to sever misjoined claims. *See* Fed. R. Civ. P. 20(a). Federal Rule of Civil Procedure 20(a) states that: "All persons may join in one action as plaintiffs if they assert any right to relief jointly, severally, or in the alternative in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all these persons will arise in the action." Rule 21 states, in part: "On motion or on its own, the court may at any time, on just terms, add or drop a party. The court may also sever any claim against a party." *See* Fed. R. Civ. P. 21; *Coleman v. Quaker Oats Co.*, 232 F.3d 1271, 1297 (9th Cir. 2000) ("Given the broad discretion with which the district court is vested to make a decision granting severance and the fact that the district court carefully weighed the arguments in favor of and against joinder, we conclude that the district court did not abuse its discretion when it granted Quaker's motion to sever the cases."); *see also Warner v. Stryker Corp.*, Civ. No. 08-6368-AA, 2009 WL 1773170, at *2 (D. Or. June 22, 2009) (severing claims of non-Oregon plaintiffs under Rule 20, ruling that plaintiffs' mere allegations of "a

common theory of liability" did not cause claims to arise from "the same transaction, occurrence or series of transactions, particularly given that *non-Oregon plaintiffs received individualized medical care in vastly different geographical regions*") (emphasis added).

104. Judge Wilson recently ruled, in an almost identical case brought by sixteen plaintiffs, that the multiple plaintiffs in that case were improperly joined and ordered each plaintiff to file a separate complaint. *See Burns,* 2013 WL 5596122 at *2. The same is true here.

105. Plaintiffs do not even allege that the Infuse Device was used in the same off-label manner in each of them. *See FAC ¶¶16-65.* In fact, almost all of the Plaintiffs' charging allegations include mention of having numerous procedures, different kinds of procedures, and different kinds of products/instrumentation implanted in their bodies in addition to the Infuse Device. *Id.* The varied off-label procedures listed in the FAC are just one example of the great factual variation between Plaintiffs' claims. For instance, in addition to mention cervical (neck) surgeries throughout the FAC, the FAC alleges there are three different ways in which the Infuse Device could be implanted in an off-label manner through the lumbar (or lower back) part of the spine. (*Id. at ¶ 139*) (describing the Posterior Lumbar Interbody Fusion, Posterolateral Fusion, and Transforaminal Lumbar Interbody Fusion approaches). Thus, on top of the individualized issues of causation, damages, witnesses, and preexisting conditions present in every product liability case, these Plaintiffs' claims vary further as to ***what*** off-label use is at issue. Under such circumstances, courts have found claims to be misjoined, and ignore the citizenship of those parties.

106. Considering their geographic diversity and the absence of any factual nexus between the Misjoined Plaintiffs and the other forty-four Plaintiffs, the Misjoined Plaintiffs' attempted joinder in this case will frustrate both the underlying purpose of the joinder rules and the Medtronic Defendants' right to removal. *See In re*

Fosamax, 2012 WL 1118780, at *5 (finding joinder of plaintiffs was "egregious" where they could claim no connection with the forum state or other plaintiffs, and ruling that the "joinder was undertaken to thwart Defendants' statutory right of removal to federal court, and therefore, Plaintiffs' claims are fraudulently misjoined"); *In re Rezulin*, 168 F. Supp. 2d at 147 ("This is not to say the cost and efficiency benefits to joined plaintiffs are immaterial; they simply do not carry the same weight when balanced against the defendant's right to removal.").

107. The Court should find that California Plaintiffs Terry Martinez, Shannon Compton, Richard Plummer, Mary Timmons, and Penny Romero, Tennessee Plaintiffs Tabathia Gates and Cynthia Gibson, New Jersey Plaintiff Anthony Mormil, New York Plaintiff John Mancuso, and Pennsylvania Plaintiffs Brenda Landis and Willie Stanberry Jr. here have been misjoined – because they have no connection whatsoever with the other Plaintiffs—and sever the actions brought by these Misjoined Plaintiffs for the purposes of maintaining the Medtronic Defendants and Wyeth's right to removal of the action involving the other plaintiffs.

108. Additionally, the Medtronic Defendants note that Plaintiff Cynthia Gibson's claims must fail because her alleged implant took place on either June 12, 2002 or January 8, 2003, both dates that fall outside Tennessee's Statute of Repose, which requires that all product liability actions "must be brought within ten (10) years from the date on which the product was first purchased for use or consumption, or within one (1) year after the expiration date of the anticipated life of the product, whichever is the shorter." *See* Tenn. Code Ann Section 29-28-103; *see also Wahl v. General Electric Company*, 2013 U.S. Dist. LEXIS 162320 at *19 (M.D. Tenn. Nov. 14, 2013). Thus, this Court should dismiss the claims of Cynthia Gibson with prejudice.

109. Defendants therefore request that this Court remand the claims of California Plaintiffs Terry Martinez, Shannon Compton, Richard Plummer, Mary Timmons, and Penny Romero, Tennessee Plaintiffs Tabathia Gates and Cynthia

Gibson (provided this Court does not dismiss her claims with prejudice under Tennessee state law), New Jersey Plaintiff Anthony Mormil, New York Plaintiff John Mancuso, And Pennsylvania Plaintiffs Brenda Landis and Willie Stanberry Jr. to the Superior Court of Los Angeles County, and retain jurisdiction over the claims of the remaining forty-four Plaintiffs' claims.

110. For the foregoing reasons, this Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, and this action is properly removed pursuant to 28 U.S.C. §§ 1441 and 1446.

III. CONCLUSION

111. **WHEREFORE**, the Medtronic Defendants pray that this action be removed from the Superior Court of the State of California for the County of Los Angeles to the United States District Court for the Central District of California.

Dated: February 7, 2014

REED SMITH LLP

By _____

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SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

Medtronic, Inc., et al (see attachement)

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

Richard Plummer, et al (see attachment)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

CONFORMED COPY
ORIGINAL FILED
Superior Court Of California
County Of Los Angeles

NOV 26 2013

Sherri R. Carter, Executive Officer/Clerk
By: Kristina Vargas, Deputy

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.

¡AVISO! Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es):

Stanley Mosk Courthouse, 111 North Hill Street, Los Angeles, CA 90012

CASE NUMBER:
(Número del caso): BC528729

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Jessica Lee, Napoli Bern Ripka Shkolnik, 1 1 Corporate Drive, Suite 225, Ladera Ranch, CA 92964

DATE: 11/26/13 *(Fecha)*

SHERRI R. CARTER

Clerk, by *(Secretario)* Kristina Vargas, Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOV 26 2013

NOTICE TO THE PERSON SERVED: You are served
1. [✓] as an individual defendant.
2. [ ] as the person sued under the fictitious name of *(specify)*:
3. [ ] on behalf of *(specify)*:
   under: [ ] CCP 416.10 (corporation)
   [ ] CCP 416.20 (defunct corporation)
   [ ] CCP 416.40 (association or partnership)
   [ ] other *(specify)*:
   [ ] CCP 416.60 (minor)
   [ ] CCP 416.70 (conservatee)
   [ ] CCP 416.90 (authorized person)
4. [ ] by personal delivery on *(date)*:

Form Adopted for Mandatory Use
Judicial Council of California
SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
www.courtinfo.ca.gov

SUM-100

SUMMONS
(CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

CONFORMED COPY
ORIGINAL FILED
Superior Court Of California
County Of Los Angeles

NOV 26 2013

Sherri R. Carter, Executive Officer/Clerk
By: Kristina Vargas, Deputy

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

Medtronic, Inc., et al (see attachement)

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

[redacted]

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.

¡AVISO! Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es):
Stanley Mosk Courthouse, 111 North Hill Street, Los Angeles, CA 90012

CASE NUMBER:
(Número del Caso): BC528729

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

[redacted]

DATE: 11/26/13 (Fecha) SHERRI R. CARTER Clerk, by (Secretario) Kristina Vargas, Deputy (Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)
(Para prueba de entrega de esta citation use el formulario Proof of Service of Summons, (POS-010)).

SEAL
NOV 26 2013

NOTICE TO THE PERSON SERVED: You are served
1. ☑ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify)*:
3. ☒ on behalf of *(specify)*: PFIZER, INC.
under: ☒ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other *(specify)*:
4. ☐ by personal delivery on *(date)*: 01/14/14

Page 1 of 1

Form Adopted for Mandatory Use
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SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
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Medtronic, Inc.,
710 Medtronic Parkway
Minneapolis, MN 55432-5604

Medtronic Sofamor Danek
1800 Pyramid Pl,
Memphis, TN 38132

Medtronic Vertilink, Inc.
CT Corporation System
818 W. Seventh Street,
Los Angeles, CA 90017

Wyeth, Inc.
500 Arcola Road
Collegeville, PA 19426

Pfizer, Inc.
10777 Science Center Drive
San Diego, California 92121

Wyeth Pharma, Inc.
500 Arcola Road
Collegeville, PA 19426

Dr. Gary Michelson
11755 Wilshire Blvd Suite 1400
Los Angeles, CA 90025

Alex Bolanos
710 Medtronic Pkwy
Minneapolis, Minnesota 55432

Kevin Bradley
710 Medtronic Pkwy
Minneapolis, Minnesota 55432

Debbie Pagach
710 Medtronic Pkwy
Minneapolis, Minnesota 55432

Maral Amiri
710 Medtronic Pkwy
Minneapolis, Minnesota 55432

CT Corporation

Service of Process Transmittal
01/13/2014
CT Log Number 524206924

TO: Vicki Tersteeg
Medtronic, Inc.
MS: LC300, 710 Medtronic Parkway
Minneapolis, MN 55432-5604

RE: **Process Served in California**

FOR: Medtronic Vertelink, Inc. (Domestic State: CA)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Richard Plummer, et al., Pltfs. vs. Medtronic, Inc., et al. including Medtronic Vertelink, Inc., Dfts.
DOCUMENT(S) SERVED:	Summons, Cover Sheet, Addendum and Statement, Notice(s), First Amended Complaint(s), Complaint(s)
COURT/AGENCY:	Los Angeles County - Superior Court - Central District, CA Case # BC528729
NATURE OF ACTION:	Product Liability Litigation - Drug Litigation - Infuse Bone Graft
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Los Angeles, CA
DATE AND HOUR OF SERVICE:	By Process Server on 01/13/2014 at 15:55
JURISDICTION SERVED :	California
APPEARANCE OR ANSWER DUE:	Within 30 calendar days after this summons and legal papers are served on you
ATTORNEY(S) / SENDER(S):	Jessica Y. Lee Napoli Bern Ripka Shkolnik & Assoc., LLP 111 Corporate Drive Suite 225 Ladera Ranch, CA 92694 949-234-6032
ACTION ITEMS:	CT has retained the current log, Retain Date: 01/14/2014, Expected Purge Date: 01/19/2014 Image SOP Email Notification, Vicki Tersteeg VICKI.ANN.TERSTEEG@MEDTRONIC.COM Email Notification, Jackie Hiltner jackie.hiltner@medtronic.com
SIGNED:	C T Corporation System
PER:	Nancy Flores
ADDRESS:	818 West Seventh Street Los Angeles, CA 90017
TELEPHONE:	213-337-4615

CT Corporation

Service of Process Transmittal
01/13/2014
CT Log Number 524206924

TO: Vicki Tersteeg
Medtronic, Inc.
MS: LC300, 710 Medtronic Parkway
Minneapolis, MN 55432-5604

RE: **Process Served in California**

FOR: Medtronic Vertelink, Inc. (Domestic State: CA)

DOCKET HISTORY:

DOCUMENT(S) SERVED:	DATE AND HOUR OF SERVICE:	TO:	CT LOG NUMBER:
First Amended Complaint, Proof of Service	By Regular Mail on 12/23/2013 at 20:23 postmarked: "Not Post Marked"	Vicki Tersteeg Medtronic, Inc.	524115104

1/13/14 @ 3:55pm

SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

Medtronic, Inc., et al (see attachement)

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

[redacted]

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(SOLO PARA USO DE LA CORTE)

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Superior Court Of California
County Of Los Angeles

NOV 26 2013

Sherri R. Carter, Executive Officer/Clerk
By: Kristina Vargas, Deputy

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The name and address of the court is:
(El nombre y dirección de la corte es):

Stanley Mosk Courthouse, 111 North Hill Street, Los Angeles, CA 90012

CASE NUMBER:
(Número del caso): BC528729

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

[redacted]

DATE: 11/26/13 (Fecha) SHERRI R. CARTER Clerk, by (Secretario) Kristina Vargas, Deputy (Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)
(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

[SEAL] NOV 26 2013

NOTICE TO THE PERSON SERVED: You are served
1. [x] as an individual defendant.
2. [ ] as the person sued under the fictitious name of *(specify)*:
3. [x] on behalf of *(specify)*: Medtronic VertiLink, Inc.
   under: [x] CCP 416.10 (corporation) [ ] CCP 416.60 (minor)
   [ ] CCP 416.20 (defunct corporation) [ ] CCP 416.70 (conservatee)
   [ ] CCP 416.40 (association or partnership) [ ] CCP 416.90 (authorized person)
   [ ] other *(specify)*:
4. [x] by personal delivery on *(date)*: 11/13/14

Page 1 of 1

Form Adopted for Mandatory Use
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SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
www.courtinfo.ca.gov

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Jessica Y. Lee
SBN 282671
Napoli Bern Ripka Shkolnik, LLP
111 Corporate Drive, Suite 225, Ladera Ranch, CA 92964
TELEPHONE NO: 949-234-6032 FAX NO: 949-429-0892
ATTORNEY FOR (Name): Richard Plummer, et al

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ORIGINAL FILED
Superior Court Of California
County Of Los Angeles
NOV 26 2013
Sherri R. Carter, Executive Officer/Clerk
By: Kristina Vargas, Deputy

SUPERIOR COURT OF CALIFORNIA, COUNTY OF Los Angeles
STREET ADDRESS: Stanley Mosk Courthouse on Hill St.
MAILING ADDRESS: 111 North Hill St.
CITY AND ZIP CODE: Los Angeles, CA 90012
BRANCH NAME: Stanley Mosk Courthouse, Central Division

CASE NAME:
Richard Plummer, et al v. Medtronic, Inc., et al

CASE NUMBER: BC528729

JUDGE:
DEPT:

CIVIL CASE COVER SHEET
- [✓] Unlimited (Amount demanded exceeds $25,000)
- [ ] Limited (Amount demanded is $25,000 or less)

Complex Case Designation
- [ ] Counter
- [ ] Joinder

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

Items 1–6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort
- [ ] Auto (22)
- [ ] Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- [ ] Asbestos (04)
- [✓] Product liability (24)
- [ ] Medical malpractice (45)
- [ ] Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- [ ] Business tort/unfair business practice (07)
- [ ] Civil rights (08)
- [ ] Defamation (13)
- [ ] Fraud (16)
- [ ] Intellectual property (19)
- [ ] Professional negligence (25)
- [ ] Other non-PI/PD/WD tort (35)

Employment
- [ ] Wrongful termination (36)
- [ ] Other employment (15)

Contract
- [ ] Breach of contract/warranty (06)
- [ ] Rule 3.740 collections (09)
- [ ] Other collections (09)
- [ ] Insurance coverage (18)
- [ ] Other contract (37)

Real Property
- [ ] Eminent domain/inverse condemnation (14)
- [ ] Wrongful eviction (33)
- [ ] Other real property (26)

Unlawful Detainer
- [ ] Commercial (31)
- [ ] Residential (32)
- [ ] Drugs (38)

Judicial Review
- [ ] Asset forfeiture (05)
- [ ] Petition re: arbitration award (11)
- [ ] Writ of mandate (02)
- [ ] Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- [ ] Antitrust/Trade regulation (03)
- [ ] Construction defect (10)
- [ ] Mass tort (40)
- [ ] Securities litigation (28)
- [ ] Environmental/Toxic tort (30)
- [ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- [ ] Enforcement of judgment (20)

Miscellaneous Civil Complaint
- [ ] RICO (27)
- [ ] Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
- [ ] Partnership and corporate governance (21)
- [ ] Other petition *(not specified above)* (43)

2. This case [✓] is [ ] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [ ] Large number of separately represented parties
   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [✓] Substantial amount of documentary evidence
   d. [✓] Large number of witnesses
   e. [✓] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. [✓] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [✓] punitive
4. Number of causes of action *(specify)*: 48
5. This case [ ] is [✓] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: 11/26/13
Jessica Y. Lee
(TYPE OR PRINT NAME) (SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Form Adopted for Mandatory Use
Judicial Council of California
CM-010 [Rev. July 1, 2007]

CIVIL CASE COVER SHEET

Cal. Rules of Court, rules 2.30, 3.220, 3.400–3.403, 3.740;
Cal. Standards of Judicial Administration, std. 3.10
www.courtinfo.ca.gov

BY FAX

SHORT TITLE	CASE NUMBER
Richard Plummer, et al. v. Medtronic Inc., et al	BC528729

CIVIL CASE COVER SHEET ADDENDUM AND STATEMENT OF LOCATION (CERTIFICATE OF GROUNDS FOR ASSIGNMENT TO COURTHOUSE LOCATION)

This form is required pursuant to Local Rule 2.0 in all new civil case filings in the Los Angeles Superior Court.

Item I. Check the types of hearing and fill in the estimated length of hearing expected for this case:

JURY TRIAL? ☑ YES CLASS ACTION? ☐ YES LIMITED CASE? ☐ YES TIME ESTIMATED FOR TRIAL 20 ☐ HOURS/ ☑ DAYS

Item II. Indicate the correct district and courthouse location (4 steps – If you checked "Limited Case", skip to Item III, Pg. 4):

Step 1: After first completing the Civil Case Cover Sheet form, find the main Civil Case Cover Sheet heading for your case in the left margin below, and, to the right in Column **A**, the Civil Case Cover Sheet case type you selected.

Step 2: Check **one** Superior Court type of action in Column **B** below which best describes the nature of this case.

Step 3: In Column **C**, circle the reason for the court location choice that applies to the type of action you have checked. For any exception to the court location, see Local Rule 2.0.

Applicable Reasons for Choosing Courthouse Location (see Column C below)

1. Class actions must be filed in the Stanley Mosk Courthouse, central district.
2. May be filed in central (other county, or no bodily injury/property damage).
3. Location where cause of action arose.
4. Location where bodily injury, death or damage occurred.
5. Location where performance required or defendant resides.
6. Location of property or permanently garaged vehicle.
7. Location where petitioner resides.
8. Location wherein defendant/respondent functions wholly.
9. Location where one or more of the parties reside.
10. Location of Labor Commissioner Office.

Step 4: Fill in the information requested on page 4 in Item III; complete Item IV. Sign the declaration.

	A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons See Step 3 Above
Auto Tort	Auto (22)	☐ A7100 Motor Vehicle - Personal Injury/Property Damage/Wrongful Death	1., 2., 4.
	Uninsured Motorist (46)	☐ A7110 Personal Injury/Property Damage/Wrongful Death – Uninsured Motorist	1., 2., 4.
Other Personal Injury/ Property Damage/ Wrongful Death Tort	Asbestos (04)	☐ A6070 Asbestos Property Damage ☐ A7221 Asbestos - Personal Injury/Wrongful Death	2. 2.
	Product Liability (24)	☑ A7260 Product Liability (not asbestos or toxic/environmental)	1., 2., 3., 4., 8.
	Medical Malpractice (45)	☐ A7210 Medical Malpractice - Physicians & Surgeons ☐ A7240 Other Professional Health Care Malpractice	1., 4. 1., 4.
	Other Personal Injury Property Damage Wrongful Death (23)	☐ A7250 Premises Liability (e.g., slip and fall) ☐ A7230 Intentional Bodily Injury/Property Damage/Wrongful Death (e.g., assault, vandalism, etc.) ☐ A7270 Intentional Infliction of Emotional Distress ☐ A7220 Other Personal Injury/Property Damage/Wrongful Death	1., 4. 1., 4. 1., 3. 1., 4.

BY FAX

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES
NOTICE OF CASE ASSIGNMENT - UNLIMITED CIVIL PERSONAL INJURY CASE

Case Number BC528729

THIS FORM IS TO BE SERVED WITH THE SUMMONS AND COMPLAINT

Your case is assigned for all purposes to the judicial officer indicated below (Local Rule 3.3(c)).

	ASSIGNED JUDGE	DEPT	ROOM
	Hon. Rafael Ongkeko	91	635
	Hon. Amy D Hogue	92	633
✓	Hon. Samantha P. Jessner	93	631

ASSIGNED JUDGE	DEPT	ROOM

Given to the Plaintiff/Cross-Complainant/Attorney of Record on NOV 26 2013 SHERRI R. CARTER, Executive Officer/Clerk

LACIV PI 190 (Rev09/13)
LASC Approved 05-06
For Optical Use

By Kristina Varges, Deputy Clerk

NOTICE OF CASE ASSIGNMENT – UNLIMITED CIVIL CASE

Jessica Y. Lee (CA SBN CA 282671)
Nicholas R. Farnolo (NY SBN 4605952)
NAPOLI BERN RIPKA SHKOLNIK & ASSOC., LLP
111 Corporate Drive, Suite 225
Ladera Ranch, California 92694
Telephone: (949) 234-6032
Facsimile: (949) 429-0892
JLee@Napolibern.com
NFarnolo@Napolibern.com
Attorneys for Plaintiffs

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF LOS ANGELES

RICHARD PLUMMER, JOHNNY BALLINGER, TIMERY UEBBING, TERRY MARTINEZ, TABATHIA GATES, SHARON WHITE, SARA MCMILLAN, ROSILAND SPENCER, RONDA HOULE, NINA VINCENT, MICHAEL MCMILLAN, MAUREEN JACQUES, LORI SHOULDERS, LEONARD HUNTER, JIMMY WEEKS, ISABEL BUCKHOLDT, DYLAN WEST, AUDRA GUERRETTAZ, HASKELL CROFT, DAWN TRUAX, SHANNON COMPSTON, DEREK DAVIS, NORVEL DICKENS, GANA BRETT, JIMMY HENDRICH, JEFFERY HINES, BRENDA LANDIS, PATRICK MCCOY, JOHN MANCUSO, MARSHA MORRIS, ANTHONY NORMIL, PIO EMILIA, NANCY SCHREIBER, WILLIE STANBERRY JR., DOUGLAS PRESTIDGE, MARYANNE WAGNER, BYOTHA THOMAS, PATRICIA SHEPARD, ROSEMARY PENTON, NICHOLAS SCHULTZ, MARY TIMMONS, MELODIE WARD, CYNTHIA GIBSON, SHEILA GOODMAN-GILBERT, KRISTAL REED, PENNY ROMERO, SHIRLEY HANEY, AND KAREN SAPPINGTON, LINDA THOMPSON, and SCOTT SMITH, Plaintiffs, vs.	Case No. BC 528729 FIRST AMENDED COMPLAINT FOR DAMAGES JURY TRIAL DEMAND 1. Products Liability – Manufacturing Defect 2. Failure to Warn 3. Strict Products Liability – Design Defect 4. Strict Products Liability – Negligence 5. Fraud 6. Intentional Misrepresentation 7. California Unfair Competition Law 8. Breach of Express and Implied Warranties 9. Negligence per se 10. Strict Liability 11. Punitive Damages BY FAX

MEDTRONIC, INC. MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC VERTELINK, INC., WYETH INC., WYETH PHARMACEUTICALS, INC., PFIZER, INC., DR. GARY K. MICHELSON, ALEX BOLANOS, KEVIN BRADLEY, DEBBIE PAGACH, MARAL AMIRI, and DOES 1 THROUGH 100, inclusive,

Defendants.

COMES NOW Plaintiffs, and each of them, and complain and allege against MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC VERTELINK, INC., (collectively referred to as "MEDTRONIC" or "MEDTRONIC DEFENDANTS"), WYETH INC., WYETH PHARMACEUTICALS, INC., PFIZER, INC., DR. GARY K. MICHELSON, ALEX BOLANOS, KEVIN BRADLEY, DEBBIE PAGACH, MARAL AMIRI, and DOES 1 THROUGH 100, each of them as follows:

COMPLAINT

GENERAL ALLEGATIONS

1. This case involves a number of spinal surgeries in which a bioengineered, liquid, bone graft device, INFUSE™ Bone Graft ("INFUSE™"), was implanted in Plaintiffs in an off-label manner.

2. The FDA classifies INFUSE ™ as a medical device. The INFUSE Bone Graft and LT-Cage (collectively known as "Infuse") is manufactured, promoted, marketed, and distributed by Defendants Medtronic, Medtronic Sofamor Danek and Medtronic Vertelink, and Wyeth, a subsidiary of Pfizer, and promoted, invented, marketed and designed, in part, by Dr. Gary Karlin Michelson.

3. INFUSE™ is used in spinal fusion surgeries, and its purpose is to fuse vertebrae of the spine together and yield the same result as implanting a patient's own bone or cadaver bone, thereby obviating the need to harvest bone from the patient's own hip and maximizing the procedure's success rate. As noted above, Infuse consists of two separate components. One component is a drug known as recombinant human bone morphogenetic protein-2 ("rhBMP-2"), which was developed and sold by Wyeth, a wholly owned subsidiary of Pfizer; this drug is placed on a collagen sponge, and delivered to health care providers, and the Plaintiff's physicians, in a separate package. The second component, also delivered in a separate package, is a metal cage device (the "LT-cage"), which was invented, in part, by Dr. Michelson. This cage acts as a scaffold to house the sponge that contains rhBMP-2.

4. This case involves a number of spinal fusion surgeries in which INFUSE™ was used in an *off-label* (e.g., not approved by the FDA) manner for a spinal fusion. The FDA approved INFUSE™ *only* for lumbar surgery that is performed through the abdomen (anterior approach) – and for some tibia fractures and specific dental surgeries irrelevant to this case. Further, the FDA approved INFUSE™ for anterior lumbar surgery only when INFUSE™ is used *in combination with* an "LT-Cage™," a hollow metal cylinder used to insert the INFUSE™ into the spine. The FDA did *not* approve INFUSE™ for use in cervical spine surgery or any non-anterior approach to lumbar surgery, such as through the back or side of the body (posterior and lateral approaches, respectively). Therefore, all cervical spine surgeries, many lumbar surgeries, and any INFUSE™ back surgery without using an LT-Cage™ are off-label uses..

5. Despite this lack of FDA approval and the FDA's explicit concerns about the dangers of off-label uses to patients, MEDTRONIC improperly promoted INFUSE™ to be used

off-label for posterior lumbar spine fusions, cervical spine fusions, and spine fusions without an LT-Cage™.

6. Patients' spine surgeons, including Plaintiffs' surgeons, were persuaded by MEDTRONIC and MEDTRONIC's consultant "opinion leaders," who are paid physician promoters, to expand their INFUSE™ use to off-label uses, such as posterior lumbar fusions and cervical spine fusions.

7. At all times relevant to this action, all persons acting on behalf of MEDTRONIC were employees and/or agents with actual, implied, or inherent authority to act on behalf of MEDTRONIC. MEDTRONIC approved or ratified all such actions of these employees and/or agents.

8. INFUSE™, and the LT-Cage,when used off-label, can cause severe injuries to the patient, including INFUSE™-induced bone overgrowth and other complications that often necessitate painful, risky, and costly revision surgeries that might not cure the problems that the INFUSE™ and the LT-Cage caused.

9. This uncontrolled bone growth (also known as "ectopic" or "exuberant" bone growth) can compress or severely damage the surrounding neurologic structures in the spine, and bone can grow onto or around the spinal cord or spinal nerve roots. When this excessive bone growth compresses the nerves, the patient can experience, among other adverse events, intractable pain, paralysis, spasms, and the need for revision surgery.

10. INFUSE™, when used off-label, can cause or contribute to other serious injuries and complications, including extreme inflammatory reactions, chronic radiculitis, retrograde ejaculation, sterility, osteolysis (bone resorption), displacement or migration of the spacer cage, pseudoarthrosis, and worse overall outcomes.

11. Notwithstanding overwhelming and substantial evidence (including MEDTRONIC-sponsored studies) demonstrating these increased risks of adverse reactions from off-label use of INFUSE™, MEDTRONIC recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these off-label risks while

promoting INFUSE™ to spine surgeons for off-label uses. In fact, MEDTRONIC promoted to spine surgeons and patients the use of INFUSE™ in dangerous off-label procedures, thereby demonstrating a conscious disregard for the health and safety of spinal fusion patients, such as the Plaintiff.

12. Moreover, the actual rate of incidence of serious side effects from off-label use of INFUSE™ is, in fact, much greater than MEDTRONIC disclosed to spine surgeons and patients. Regarding the off-label approaches, MEDTRONIC failed to accurately disclose the significant off-label risks that it knew or should have known.

13. Because of MEDTRONIC's wrongful conduct in actively and illegally promoting the off-label uses of INFUSE™ and because of MEDTRONIC's additional wrongful conduct in minimizing, concealing, and/or downplaying the true risks of these non-FDA approved off-label uses of MEDTRONIC's INFUSE™, thousands of spine patients, including Plaintiff, underwent surgeries without knowing the true risks inherent in the off-label use of INFUSE™.

14. These patients and their physicians relied on MEDTRONIC's false and misleading statements of material fact including statements and publications by MEDTRONIC's "opinion leaders," "thought leaders," and sales representatives. MEDTRONIC orchestrated a marketing campaign from at least 2002 to the present to persuade spine surgeons to use INFUSE™ in dangerous off-label uses in the spine. Indeed, absent MEDTRONIC's extensive off-label promotion campaign, physicians, such as the Plaintiff's spine surgeon, would never have performed these especially risky off-label procedures.

15. As a result of off-label INFUSE™ surgery using off-label procedures and/or components, Plaintiff suffered bodily injuries and damages as described herein.

PARTIES

PLAINTIFFS

16. Plaintiff TERRY MARTINEZ is an adult individual who at all times relevant hereto was residing in the State of California. On December 22, 2009, Plaintiff TERRY MARTINEZ presented at Good Samaritan Hospital, where Dr. David Yeh performed a surgical

procedure: the transfemoral lumbar interbody arthrodesis at L5-S1, the placement of crescent PEEK cage at L5-S1, the posterolateral arthrodesis at L5-S1, the non-segmental pedicle screw instrumentation at L5-S1, and the placement of allograft for fusion. On October 12,2010, Plaintiff presented at Good Samaritan Hospital, where Dr. David Yeh performed a second surgical procedure: the redoing posterior lumbar interbody fusion at L5-S1 from the right, the segmental pedicle screw instrumentation at L4, L5, and S1 bilaterally, and the placement of morselized autograft, as well as allograft for fusion. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this lumbar fusion surgery, Plaintiff TERRY MARTINEZ now suffers from severe injuries and damages, including but not limited to difficulty standing, chronic pain syndrome, left leg dysesthesias, neck and shoulder pain with radiculopathy, cord compression, dysthymia, depression, headaches, incapacitating pain, suicidal thoughts, anxiety, narcotic dependence from prescribed painkillers, other emotional distress and mental anguish, and suboccipital, lumbosacral, cervical, and shoulder myofascial syndromes. December 2011 was the first time that Plaintiff TERRY MARTINEZ had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff TERRY MARTINEZ did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until the December 2011 at the earliest.

17. Plaintiff JOHNNY BALLINGER is an adult individual who at all times relevant hereto was residing in the State of Kentucky. On January 29, 2008, Plaintiff JOHNNY BALLINGER presented at Norton Hospital, where Dr. Steven Glassman performed a surgical procedure: the anterior cervical discectomy and fusion from C4-C6. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in in this cervical fusion surgery, Plaintiff JOHNNY BALLINGER now suffers from severe neck and back pain,

including difficulty swallowing, chronic pain syndrome, suicidal thoughts and anxiety, and narcotic dependence from prescribed painkillers. February 2013 was the first time that Plaintiff JOHNNY BALLINGER should have had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JOHNNY BALLINGER did not know and his injury could not have been known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until February 2013 at the earliest.

18. Plaintiff TIMERY UEBBING is an adult individual who at all times relevant hereto was residing in the State of Michigan. On August 13, 2007, Plaintiff TIMERY UEBBING presented at Oakwood Hospital, where Dr. Fredrick Junn performed a surgical procedure: the cord compression secondary to herniated disc at C6-7, the posterior portion of the discectomy, and the congenital fusion C5-6. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in in this cervical fusion surgery, Plaintiff TIMERY UEBBING now suffers from severe injuries and damages including neck pain, cervical radiculopathy, and 15-20 types cancer. July 2012 was the first time that Plaintiff TIMERY UEBBING had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff TIMERY UEBBING did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until July 2012 at the earliest.

19. Plaintiff TABATHIA GATES is an adult individual who at all times relevant hereto was residing in the State of Tennessee. On December 23, 2009, Plaintiff TABATHIA GATES presented at Skyridge Medical Center, where Dr. Rickey Hutcheson performed a surgical procedure: the anterior cervical discectomy at C7 and arthrodesis at C6-7, the anterior cervical plating using the Pioneer plating system C6 to C7 using an anterior cervical plate, the cage insertion, and the allografting using Vitoss allograft. On January 20, 2010, Plaintiff

TABATHIA GATES presented at Skyridge Medical Center, where Dr. Rickey Hutcheson performed a second surgical procedure: the decompression laminectomy at L5, the anterior discectomy of L5-S1 from the posterior side, the anterior interbody fusion L5-S1 using allograft, autograft, and INFUSE™ and the LT-cage in an off label manner in the posterior lateral fusion at L5-S1, and the posterior lateral instrumentation at L5-S1. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical and lumbar fusion surgery, Plaintiff TABATHIA GATES now suffers from severe injuries and damages, including neck pain, back pain, chest pain, headache, herniated bulging discs, bulging discs, and unwanted bone growth. April 2013 was the first time that Plaintiff TABATHIA GATES had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff TABATHIA GATES did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the end of April 2013 at the earliest.

20. Plaintiff SHARON WHITE is an adult individual who at all times relevant hereto was residing in the State of Florida. On February 27, 2009, Plaintiff SHARON WHITE presented at Broward Health, where Dr. Gary Gieseke performed a surgical procedure: the anterior cervical discectomy, the bilateral foraminotomy of nerve roots and dural sac with arthrodesis using PEEK cages/INFUSE, and the zephyr plating C5, C6, and C7. Plaintiff SHARON WHITE later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical fusion surgery, Plaintiff SHARON WHITE now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, desiccated spinal discs, cardiovascular injuries, liver damage, unwanted bone growth, cyst formation, herniated bulging discs, bulging discs, muscloskeletal injuries, deterioration of the spine, anxiety, and narcotic

dependence from prescribed painkillers. October 2012 was the first time that Plaintiff SHARON WHITE had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHARON WHITE did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until October 2012 at the earliest.

21. Plaintiff SARA MCMILLAN is an adult individual who at all times relevant hereto was residing in the State of Ohio. On April 6, 2010, Plaintiff SARA MCMILLAN presented at Mount Carmel New Albany Hospital, where Dr. Larry Todd performed a first surgical procedure: the laminectomy decompression with excision of disk protrusions at both the L3-4 and L4-5 levels, the posterior spinal fusion instrumentation with interbody allograft at the L3-4, L4-5 levels, and INFUSE™ and the LT-cage for the posterior fusion part of the procedure at the L3-4, L4-5 levels. On June 6, 2013, Plaintiff SARA MCMILLAN presented at Mount Carmel New Albany Hospital, where Dr. Larry Todd performed a second surgical procedure: the removal of hardware with exploration of fusion mass with findings of a pseudoarthrosis from the L3 to L5 level and the repeating uninstrumented posterolateral fusion from the L3 to L5 level. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this lumbar fusion surgery, Plaintiff SARA MCMILLAN now suffers from severe injuries and damages, including difficulty swallowing, chronic back pain, incapacitating pain, and narcotic dependence from prescribed painkillers. March 2013 was the first time that Plaintiff SARA MCMILLAN had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SARA MCMILLAN did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the March 2013 at the earliest.

22. Plaintiff ROSILAND SPENCER is an adult individual who at all times relevant hereto was residing in the State of Alabama. On September 20, 2007, Plaintiff ROSILAND

SPENCER presented at Helen Keller Hospital, where Dr. James Jerry Adderholt performed a surgical procedure: the anterior cervical discectomy and fusion using cornerstone interbody graft and Atlantis anterior cervical plate at C5-C7 levels. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical fusion surgery, Plaintiff ROSILAND SPENCER now suffers from severe injuries and damages. June 2013 was the first time that Plaintiff ROSILAND SPENCER had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff ROSILAND SPENCER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the June 2013 at the earliest.

23. Plaintiff RONDA HOULE is an adult individual who at all times relevant hereto was residing in the State of Georgia. Plaintiff RONDA HOULE presented at the Regional Medical Center in Madisonville, KY, where Dr. James Donley performed two decompressive laminectomies – one on n December 15, 2005, and the other on February 10, 2006. Then, on October 30, 2006, Plaintiff RONDA HOULE presented at Southern Hills Medical center, where Dr. Thomas Jeff O'Brien performed a surgical procedure: the revision L4-L5 decompression with instrumented spinal fusion/TLIF. On December 19, 2007, Plaintiff RONDA HOULE presented at Texas Back Institute, where Dr. William D Bradley performed a surgical procedure: the revision decompression at right L5, the additional level decompression at L4, the additional level decompression at L6, and the intraoperative use of microscope. Plaintiff RONDA HOULE later returned home, but her pain and difficulties standing and sitting did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this lumbar fusion surgery, Plaintiff RONDA HOULE now suffers from severe injuries and damages, including chronic pain syndrome, difficulties walking, difficulties standing, difficulties sitting,

difficulties sleeping, and narcotic dependence from prescribed painkillers. December 2012 was the first time that Plaintiff RONDA HOULE had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff RONDA HOULE did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the end of December 2012 at the earliest.

24. Plaintiff NINA VINCENT is an adult individual who at all times relevant hereto was residing in the State of Alabama. On January 27, 2010, Plaintiff NINA VINCENT presented at Huntsville Hospital, where Dr. Larry M. Parker performed a surgical procedure: the decompressive laminectomy with right L4 and L5 foraminotomies, the posterolateral fusion, L4-5, and the posterior instrumentation, L4-5 with spinal USA titanium hardware. On February 03, 2010, Plaintiff NINA VINCENT presented at Huntsville Hospital, where Dr. Larry M. Parker and Richard R. Randall performed a surgical procedure: the anterior retroperitoneal exposure and the anterior interbody fusion of L4-5. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this lumbar fusion surgery, Plaintiff NINA VINCENT now suffers from severe injuries and damages. January 2013 was the first time that Plaintiff NINA VINCENT had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff NINA VINCENT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until January 2013 at the earliest.

25. Plaintiff MICHAEL MCMILLAN is an adult individual who at all times relevant hereto was residing in the State of Ohio. On March 9, 2010, Plaintiff MICHAEL MCMILLAN presented at Mount Carmel New Albany Hospital, where Dr. Larry Todd performed a surgical procedur utilizing INFUSE™ and the LT-cage in an off label manner in a posterior approach of the procedure at the L4-5 and L5-S1 level. After the surgery, his pain and difficulties standing

did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this lumbar fusion surgery, Plaintiff MICHAEL MCMILLAN now suffers from severe injuries and damages including difficulty standing, chronic pain syndrome, occipital neuralgia, back pain, and neck pain. March 2012 was the first time that Plaintiff MICHAEL MCMILLAN had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff MICHAEL MCMILLAN did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until the end of March 2012 at the earliest.

26. Plaintiff MAUREEN JACQUES is an adult individual who at all times relevant hereto was residing in the State of Connecticut. On July 13, 2006, Plaintiff MAUREEN JACQUES presented at New Britain General Hospital, where Dr. Ahmed M. Khan and Lane Spero performed a surgical procedure: a posterior cervical fusion C4-5, C5-6, and C6-7 and the use of morcellized allograft. Plaintiff MAUREEN JACQUES later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical fusion surgery, Plaintiff MAUREEN JACQUES now suffers from severe injuries and damages, including chronic pain syndrome, neck pain, back pain, leg pain, and shoulder pain. October 2012 was the first time that Plaintiff MAUREEN JACQUES had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MAUREEN JACQUES did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until October 2012 at the earliest.

27. Plaintiff LORI SHOULDERS is an adult individual who at all times relevant hereto was residing in the State of Illinois. On January30, 2002, Plaintiff LORI SHOULDERS had a first posterior cervical fusion surgery at the C5-7 levels at Methodist Hospital. On October

3, 2002, Plaintiff LORI SHOULDERS presented at Deaconess Hospital, where Dr. Matthew B. Kern performed a second surgical procedure: the removal and replacement of left C6 lateral mass screw of left C5 and the lateral mass screw removal and placement of Infuse and cancellus bone left and refusion of left C6-7 facet with placement of Infuse and cansellus bone. After the second surgery, her neck pain did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical fusion surgery, Plaintiff LORI SHOULDERS now suffers from severe injuries and damages, including difficulty standing, chronic neck pain, incapacitating pain, and narcotic dependence from prescribed painkillers. June 2012 was the first time that Plaintiff LORI SHOULDERS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff LORI SHOULDERS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the June 2012 at the earliest.

28. Plaintiff LEONARD HUNTER is an adult individual who at all times relevant hereto was residing in the State of Missouri. On April 30, 2008, Plaintiff LEONARD HUNTER presented at Barnes Jewish Hospital, where Dr. Timothy R. Kuklo performed a surgical procedure: the anterior cervical diskectomy and fusion of the C3-C6, the bilateral foraminotomy at C3-C4 and C5-C6, the bilateral laminotomy at C4-C5, and the placement of an anterior cervical plate C4-C6. After his operation, he had a different type of injuries. Plaintiff LEONARD HUNTER later returned home, but his pain and difficulties breathing and swallowing did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical fusion surgery, Plaintiff LEONARD HUNTER now suffers from severe injuries and damages, including difficulties swallowing and breathing, difficulties sleeping, a swollen throat, choking, neck pain, bilateral arm pain and tingling, esophageal fibrotic changes, and inflammatory changes. March 2012 was the first time that Plaintiff LEONARD HUNTER

had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff LEONARD HUNTER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until the end of March 2012 at the earliest.

29. Plaintiff JIMMY WEEKS is an adult individual who at all times relevant hereto was residing in the State of Mississippi. On July 24, 2007, Plaintiff JIMMY WEEKS presented at Greenwood Leflore Hospital, where Dr. Remi Nader performed a surgical procedure: the L5-S1 lumbar interbody fusion using the bone autograft, the L5-S1 bilateral pedicle screw fixation and Medtronic screws, and the use of infuse bone morphogenic protein for interbody arthrodesis. On September 12, 2007, Plaintiff JIMMY WEEKS presented at Greenwood Leflore Hospital, where Dr. Remi Nader performed a second surgical procedure: the L5, partical S1 and partical L4 bilateral laminectomises and decompression and the redo L5-S1 left sided foraminotomies. Plaintiff JIMMY WEEKS later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this lumbar fusion surgery, Plaintiff JIMMY WEEKS now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, chest pain, lumbar radiculopathy, myofascial pain, cervical radiculopathy, anxiety, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff JIMMY WEEKS had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JIMMY WEEKS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until May 2012 at the earliest.

30. Plaintiff ISABEL BUCKHOLDT is an adult individual who at all times relevant hereto was residing in the State of Texas. On October 30, 2006, Plaintiff ISABEL BUCKHOLDT had a first surgical operation to release her back and leg pain at Southwest Texas Methodist Hospital, where Dr. Lloyd A. Youngblood made the surgery: the anterior discectomy,

interbody fusion, and plating from C4 to C7. On May 24, 2007, Plaintiff ISABEL BUCKHOLDT presented at Southwest Texas Methodist Hospital, where Dr. Robert G Johnson and Lloyd A. Youngblood performed a second surgical procedure: the L4 to S1 decompression, internal fixation and fusion, utlizing INFUSE™ and the LT-cage in an off label manner. Ms. Buckholdt has continued her pain management with Dr. Whiting, Dr. Sharma, and Stephanie Jones for 6 years, but her main problem is the chronic cervical and low-back pain. As a direct and proximate result of the use of INFUSE™ and the LT-cage in an off label manner in this cervical and lumbar fusion surgery, Plaintiff ISABEL BUCKHOLDT now suffers from severe injuries and damages, including difficulty standing, chronic back and neck pain, incapacitating pain, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff ISABEL BUCKHOLDT had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff ISABEL BUCKHOLDT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the August 2012 at the earliest.

31. Plaintiff DYLAN WEST is an adult individual who at all times relevant hereto was residing in the State of Ohio. On April 07, 2008, Plaintiff DYLAN WEST presented at Cincinnati Children's Hospital Medical Center, where Dr. A. Atiq Durrani performed a surgical procedure: the T8-9 interbody fusion with cage, and the hemilaminotomy of T8 and a decompression, and the T7 to T10 posterior spinal fusion and instrumentation with auto/allograft bone graftin, including utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff DYLAN WEST later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this thoracic fusion surgery, Plaintiff DYLAN WEST now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, chest pain, spinal fractures, desiccated spinal discs, cyst formation, herniated

bulging discs, bulging discs, musculoskeletal injuries, deterioration of the spine, anxiety, and narcotic dependence from prescribed painkillers. July 2012 was the first time that Plaintiff DYLAN WEST had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff DYLAN WEST did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until July 2012 at the earliest.

32. Plaintiff AUDRA GUERRETTAZ is an adult individual who at all times relevant hereto was residing in the State of Washington. On June 05, 2009, Plaintiff AUDRA GUERRETTAZ presented at Kaiser Permanente, where Dr. Charles Wrobel performed a surgical procedure: the anterior cervical disc excision and fusion C5-6 and C6-7, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff AUDRA GUERRETTAZ later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff AUDRA GUERRETTAZ now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, arm pain, leg pain, shoulder pain, unwanted bone growth, herniated bulging discs, bulging discs, obesity, deterioration of the spine, anxiety, and narcotic dependence from prescribed painkillers. September 2012 was the first time that Plaintiff AUDRA GUERRETTAZ had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff AUDRA GUERRETTAZ did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until September 2012 at the earliest.

33. Plaintiff HASKELL CROFT is an adult individual who at all times relevant hereto was residing in the State of Georgia. On December 15, 2008, Plaintiff HASKELL CROFT presented at Memorial Hospital, where Dr. Scott Hodges performed a surgical procedure: the transforaminal interbody cage insertion (Capstone cage with BMP) L4-5, L5-S1 and the

posterior lateral interbody fusion with local bone graft L4-5, L5-S1. On March 23, 2011, Plaintiff HASKELL CROFT presented at Memorial Hospital, where Dr. Scott Hodges performed a second surgical procedure: the left L5 complete facetectomy and the hardware removal left L5 to S1, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff HASKELL CROFT later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff HASKELL CROFT now suffers from severe injuries and damages, including chronic pain syndrome, hip pain, leg pain, unwanted bone growth, anxiety, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff HASKELL CROFT had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff HASKELL CROFT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until August 2012 at the earliest.

34. Plaintiff DAWN TRUAX is an adult individual who at all times relevant hereto was residing in the State of Colorado. On February 15, 2006, Plaintiff DAWN TRUAX presented at Vail Valley Medical Center, where Dr. Donald Corenman performed a surgical procedure: the L5-S1 TLIF with local bone, BNP and cage, posterior fusion with local bone, BNP and TSRH, instrumentation. On October 02, 2012, Plaintiff DAWN TRUAX presented at St. Anthony Hospital, where Dr. John S. Nichols performed a surgical procedure: the anterior cervical discectomy and interbody fusion using bone bank bone at C4-5, C5-6 and C6-7 with anterior titanium Atlantis plating, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff DAWN TRUAX later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in these lumbar and cervical fusion surgeries, Plaintiff DAWN TRUAX now suffers from severe injuries and damages, including

chronic pain syndrome, neck pain, back pain, unwanted bone growth, herniated bulging discs, deterioration of the spine, cervical radiculopathy, anxiety, and narcotic dependence from prescribed painkillers. August 2013 was the first time that Plaintiff DAWN TRUAX had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff DAWN TRUAX did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until August 2013 at the earliest.

35. Plaintiff SHANNON COMPTON is an adult individual who at all times relevant hereto was residing in the State of California. On June 04, 2007, Plaintiff SHANNON COMPTON presented at Sierra Vista Regional Medical Center, where Dr. Donald A. Ramberg performed a surgical procedure: the anterior cervical discectomy at C5-6, anterior cervical fusion at C5-6 using INFUSE™ and the LT-cage in an off label manner, and anterior cervical plating at C5-6 using atomic cervical plate. Plaintiff SHANNON COMPTON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff SHANNON COMPTON now suffers from severe injuries and damages, including chronic pain syndrome, neck pain hand pain, arm pain, carpal tunnel syndrome, thoracic outlet syndrome, wrist pain, numbness, deterioration of the spine, cervical radiculopathy, anxiety, and narcotic dependence from prescribed painkillers. April 2013 was the first time that Plaintiff SHANNON COMPTON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHANNON COMPTON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2013 at the earliest.

36. Plaintiff DEREK DAVIS is an adult individual who at all times relevant hereto was residing in the State of Ohio. On April 27, 2010, Plaintiff DEREK DAVIS presented at

White Plains Hospital Center, where Dr. Jack Stern performed a surgical procedure: the microlumbar discectomy with removal of an extruded disk fragment at L4-5 on the left. On February 8, 2011, Plaintiff DEREK DAVIS presented at White Plains Hospital Center, where Dr. Seth Neubardt performed a surgical procedure: the posterior lumbar interbody fusion L4-5 and L5-S1 using interbody cage device with local autogenous bone graft and with synthetic bone graft product with bone marrow aspirate with pedicle screw instrumentation left L4-L5-S1 and posterolateral fusion under fluoroscopic guidance with intraoperative running and evoked nerve monitoring. On December 8, 2012, Plaintiff DEREK DAVIS presented at White Plains Hospital Center, where Dr. Seth Neubardt performed a surgical procedure: the removal of hardware left side L4, L5, and S1 with exploration of fusion mass under fluoroscopic guidance, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff DEREK DAVIS later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff DEREK DAVIS now suffers from severe injuries and damages, including chronic pain syndrome, low back and buttock pain, leg pain, deterioration of the spine, bulging discs, anxiety, depression, and narcotic dependence from prescribed painkillers. December 2012 was the first time that Plaintiff DEREK DAVIS had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff DEREK DAVIS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until December 2012 at the earliest.

37. Plaintiff NORVEL DICKENS is an adult individual who at all times relevant hereto was residing in the State of Texas. On July 8, 2010, Plaintiff NORVEL DICKENS presented at Huntsville Hospital, where Dr. Cyrus Ghavam performed a surgical procedure: the anterior cervical fusion at C5-6, the insertion of a spinal USA PEEK cage at C5-6 filled with

INFUSE™ in an off label manner. the anterior cervical hardware removal, and the anterior cervical plating at C5-6 using spinal USA plate with screws. Plaintiff NORVEL DICKENS later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff NORVEL DICKENS now suffers from severe injuries and damages, including chronic pain syndrome, neck pain, unwanted bone growth, cyst formation, hernia, obstruction of airway, anxiety, and narcotic dependence from prescribed painkillers. April 2012 was the first time that Plaintiff NORVEL DICKENS had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff NORVEL DICKENS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until April 2012 at the earliest.

38. Plaintiff GANA BRETT is an adult individual who at all times relevant hereto was residing in the State of Nebraska. On July 12, 2010, Plaintiff GANA BRETT presented at Nebraska Orthopaedic Hospital, where Dr. Robert Zadalis and Jonathan Fuller performed a surgical procedure: the anterior L4-S1 diskectomy and fusion via a left retroperitoneal incision utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff GANA BRETT later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff GANA BRETT now suffers from severe injuries and damages, including chronic pain syndrome, low back pain, left flank and abdominal pain, unwanted bone growth, anxiety, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff GANA BRETT had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff GANA BRETT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until August 2012 at the earliest.

39. Plaintiff JIMMY HENDRICH is an adult individual who at all times relevant hereto was residing in the State of Missouri. On January, 4, 2008, Plaintiff JIMMY HENDRICH presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the T7-T8 posterior spinal fusion with instrumentation, the augmentation of posterior spinal fusion with local bone graft, and the right T7-T8 laminotomy, foraminotomy, and discectomy. On March, 28, 2008, Plaintiff JIMMY HENDRICH presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the right C4-C5 posterior cervical fusion, the right C5-C6 foraminotomy, and the augmentation of posterior cervical fusion with bone morphogenic protein and local bone graft. On January, 21, 2009, Plaintiff JIMMY HENDRICH presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the T3-T4 and T5-T6 laminectomy foraminotomy and diskectomy, the T3-T4 and T5-T6 anterior spinal fusion with placement of local bone graft, and the posterior spinal fusion at T3-T8 utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff JIMMY HENDRICH later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical and thoracic fusion surgery, Plaintiff JIMMY HENDRICH now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, arm pain, shoulder pain, numbness and tingling, anxiety, and narcotic dependence from prescribed painkillers. January 2012 was the first time that Plaintiff JIMMY HENDRICH had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JIMMY HENDRICH did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until January 2012 at the earliest.

40. Plaintiff JEFFERY HINES is an adult individual who at all times relevant hereto was residing in the State of Kentucky. On January 13, 2009, Plaintiff JEFFERY HINES

presented at Norton Hospital, where Dr. David P. Rouben performed a surgical procedure: the left-sided transforaminal posterior interbody fusion L3-4, L4-5, and L5-S1, the pedicle instrumentation L3, L4, L5, and S1 bilateral, the posterior spinal fusion L3-4, L4-5, and L5-S1, and the cage instrumentation L3-4, L4-5, and L5-S1 utilizing INFUSE™ and the LT-cage in an off label manner. On January 23, 2009, Plaintiff JEFFERY HINES presented at Norton Hospital, where Dr. David P. Rouben performed a second surgical procedure: the reinsertion of new left S1 pedicle screw and the complex closure of deep wound, postoperative wound, and lumbosacral fusion. Plaintiff JEFFERY HINES later returned home, but his back and leg pain and weakness did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff JEFFERY HINES now suffers from severe injuries and damages, including chronic pain syndrome, left leg pain, low back pain, left leg numbness, muscle spasms, right foot symptoms, left leg symptoms and narcotic dependence from prescribed painkillers. January 2013 was the first time that Plaintiff JEFFERY HINES had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JEFFERY HINES did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until January 2013 at the earliest.

41. Plaintiff BRENDA LANDIS is an adult individual who at all times relevant hereto was residing in the State of Pennsylvania. On April 18, 2008, Plaintiff BRENDA LANDIS presented at Geisinger Medical Center, where Dr. Darren Jacobs performed a surgical procedure: the L4-S1 interbody fusion with PEEK structural cage using Capstone Medtronic graft filled with Infuse rhBMP (bone morghogenic protein), the LT-Cage and morcellized autograft and the bilateral lateral allograft fusion using Infuse rhBMP (recombinant human morphogenic protein). On January 8, 2010, Plaintiff presented at Geisinger Medical Center,

where Dr. Darren Jacobs performed a second surgical procedure: the thoracic laminotomy and placement of dorsal column stimulator epidural electrodes and the programming of dorsal column stimulator device. Plaintiff BRENDA LANDIS later returned home, but her back and leg pain did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff BRENDA LANDIS now suffers from severe injuries and damages, including chronic pain syndrome, leg pain, back pain, unwanted bone growth, obesity, cyst formation, bulging discs, and narcotic dependence from prescribed painkillers. April 2013 was the first time that Plaintiff BRENDA LANDIS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff BRENDA LANDIS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2013 at the earliest.

42. Plaintiff PATRICK MCCOY is an adult individual who at all times relevant hereto was residing in the State of Texas. On September 10, 2007, Plaintiff PATRICK MCCOY presented at Pine Creek Surgery Center, where Dr. John Milani performed a surgical procedure: the laminectomy and discectomy at L3 and L4, posterior lumbar interbody fusion at L3 and L4, the placement of hardware from L3 to L5 bilaterally, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff PATRICK MCCOY later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff PATRICK MCCOY now suffers from severe injuries and damages including severe back pain. July 2012 was the first time that Plaintiff PATRICK MCCOY had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff PATRICK MCCOY did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until July 2012 at the earliest.

43. Plaintiff JOHN MANCUSO is an adult individual who at all times relevant hereto was residing in the State of New York. On April 4, 2008, Plaintiff JOHN MANCUSO presented at Beth Israel Medical Center, where Dr. Paul Kuflik performed a surgical procedure: the posterior spine fusion at L4-L5 and L5-S1 segment fixation using CD-LEGACY and the injection of intrathecal duramorph; the osteotomy L4-L5, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff JOHN MANCUSO later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff JOHN MANCUSO now suffers from severe injuries and damages including severe back pain. July 2012 was the first time that Plaintiff JOHN MANCUSO had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JOHN MANCUSO did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until July 2012 at the earliest.

44. Plaintiff MARSHA MORRIS is an adult individual who at all times relevant hereto was residing in the State of Georgia. On July 23, 2009, Plaintiff MARSHA MORRIS presented at Gwinnet Medical Center, where Dr. Douglas Kasow performed a surgical procedure: the anterior lumbar decompression at L5-S1, the anterior lumbar arthrodesis at L1-S1, the insertion of spinal cage prosthesis at L5-S1, the anterior segmental instrumentation at L5-S1, and the utilization of fluoroscopy for localization and instrumentation, thus utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff MARSHA MORRIS later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff MARSHA MORRIS now suffers from severe injuries and damages. April 2012 was the first time that Plaintiff MARSHA MORRIS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MARSHA MORRIS did not

know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2012 at the earliest.

45. Plaintiff ANTHONY MORMIL is an adult individual who at all times relevant hereto was residing in the State of New Jersey. On March 2, 2004, Plaintiff ANTHONY MORMIL presented at West Jersey Hospital, where Dr. Kamaldeep Momi performed a surgical procedure: the bilateral C3 to C7 keyhole foraminotomies with revision foraminotomy at C3-C4 bilaterally, the C6-C7 laminectomy, the C4-C7 lateral mass screw fixation, and the C4-C7 fusion utilizing crushed allograft, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff ANTHONY MORMIL later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff ANTHONY MORMIL now suffers from severe injuries and damages including neck pain, back pain, shoulder pain, male infertility, neck fractures, infection in the neck and bank, bulging discs, obstruction of airway, deterioration of the spine, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff ANTHONY MORMIL had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff ANTHONY MORMIL did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until May 2012 at the earliest.

46. Plaintiff PIO EMILIA is an adult individual who at all times relevant hereto was residing in the State of Florida. On July 24, 2006, Plaintiff PIO EMILIA presented at Coral Gables Hospital, where Dr. Allan Jorge performed a surgical procedure: the L3- S1 pedicle fusion and decompression, the L4-5 discectomy and interbody fusion, the far lateral arthrodesis at L3-S1, and the bilateral laminectomies from L3-5, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff PIO EMILIA later returned home, but her pain and difficulties did not

subside As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff PIO EMILIA now suffers from severe injuries and damages including chronic pain syndrome, muscle spasticity, back pain, neck pain, hip pain, groin pain, burning and stabbing pain, tenderness and numbness in the leg, unwanted bone growth, anxiety, depression, and narcotic dependence from prescribed painkillers. February 2012 was the first time that Plaintiff PIO EMILIA had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff PIO EMILIA did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2012 at the earliest.

47. Plaintiff NANCY SCHREIBER is an adult individual who at all times relevant hereto was residing in the State of Georgia. On March 21, 2005, Plaintiff NANCY SCHREIBER presented at Emory University Hospital, where Dr. John Heller performed a surgical procedure: the anterior interbody fusion at C4-C5 and C5-C6, the anterior cervical discectomies at C4-C5 and C5-C6, and the anterior spinal instrumentation with Atlantic plate at C4 to C6, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff NANCY SCHREIBER later returned home, but her pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff NANCY SCHREIBER now suffers from severe injuries and damages including chronic pain syndrome, back pain, anxiety, depression, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff NANCY SCHREIBER had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff NANCY SCHREIBER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until August 2012 at the earliest.

48. Plaintiff WILLIE STANBERRY JR. is an adult individual who at all times relevant hereto was residing in the State of Pennsylvania. On October 29, 2009, Plaintiff WILLIE STANBERRY JR. presented at Cleveland Clinic, where Dr. Teresa Ruch performed a surgical procedure: the laminectomy and foraminotomies bilaterally utilizing INFUSE™ and the LT-cage in an off label manner to treat L4-5 stenosis and L5-S1 spondylolisthesis and spondylolysis with degenerative disk disease. Plaintiff WILLIE STANBERRY JR. later returned home, but his pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff WILLIE STANBERRY JR. now suffers from severe injuries and damages including chronic pain syndrome, neck pain, back pain, anxiety, depression, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff WILLIE STANBERRY JR. had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff WILLIE STANBERRY JR. did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until August 2012 at the earliest.

49. Plaintiff DOUGLAS PRESTIDGE is an adult individual who at all times relevant hereto was residing in the State of Arizona. On August 12, 2004, Plaintiff DOUGLAS PRESTIDGE presented at Southern Arizona VA Health Care, where Dr. Karsten Fryburg performed a surgical procedure: the anterior cervical discectomy at C5-C6 and C6-C7 with harvesting of iliac crest bone graft and the arthrodesis at C5-6 and C6-7 with plating utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff DOUGLAS PRESTIDGE later returned home, but his pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff DOUGLAS PRESTIDGE now suffers from severe injuries and damages including chronic pain syndrome, neck pain, back pain,

desiccated spinal discs, cyst formation, bulging discs, unwanted bone growth, obstruction of airway, deterioration of the spine, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff DOUGLAS PRESTIDGE had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff DOUGLAS PRESTIDGE did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until May 2012 at the earliest.

50. Plaintiff MARYANNE WAGNER is an adult individual who at all times relevant hereto was residing in the State of Illinois. On December 8, 2009, Plaintiff MARYANNE WAGNER presented at Centennial Medical Center, where Dr. Jacob Schwarz performed a surgical procedure: the C3 to C7 anterior cervical discectomy and fusion, utilizing INFUSE™ and the LT-cage in an off label manner. On February 23, 2010, Plaintiff MARYANNE WAGNER presented at Centennial Medical Center, where Dr. Jacob Schwarz performed a surgical procedure: the one-level L4 to S1 transforaminal lumbar interbody fusion. Plaintiff MARYANNE WAGNER later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar and cervical fusion surgery, Plaintiff MARYANNE WAGNER now suffers from severe injuries and damages, including foraminal stenosis, facet hypertrophy, difficulty walking, chronic pain syndrome, lumbar spondylolysis, cervical spodylolysis, neck pain, bilateral arm pain, low back pain, bilateral leg pain, numbness, tingling, lumber radiculopathy, and spinal fractures. April 2012 was the first time that Plaintiff MARYANNE WAGNER had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MARYANNE WAGNER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2012 at the earliest.

51. Plaintiff BYOTHA THOMAS is an adult individual who at all times relevant hereto was residing in the State of Ohio. On July 29, 2004, Plaintiff BYOTHA THOMAS presented at Florida Hospital, where Dr. Richard Smith performed a surgical procedure: the posterior lumbar interbody fusion at L5-S1, the insertion of cages and vertebral body defects at L5-S1, the insertion of segmental spinal instrumentation and lumbar spine, the bilateral posterolateral fusion at L5-S1, utilizing INFUSE™ and the LT-cage in an off label manner.. Plaintiff BYOTHA THOMAS later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff BYOTHA THOMAS now suffers from severe injuries and damages including chronic pain syndrome, back pain, spinal fractures, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff BYOTHA THOMAS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff BYOTHA THOMAS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until May 2012 at the earliest.

52. Plaintiff PATRICIA SHEPARD is an adult individual who at all times relevant hereto was residing in the State of North Carolina. On May 23, 2007, Plaintiff PATRICIA SHEPARD presented at New Hanover Regional Medical Center, where Dr. George Huffmon performed a surgical procedure: the C3-C7 anterior cervical disckectomy and arthrodesis, the verte-stack interbody spacers, the ant-cer plate C3-C7, and the left iliac crest bone marrow aspirate, grafton local autograft, and microscope with fluoroscopy, utilizing INFUSE™ and the LT-cage in an off label manner. On June 4, 2008, Plaintiff PATRICIA SHEPARD presented at New Hanover Regional Medical Center, where Dr. George Huffmon performed a surgical procedure: the C3, C4, C5, C6, and C7 posterior cervical fusion. On April 28, 2011, Plaintiff

PATRICIA SHEPARD presented at New Hanover Regional Medical Center, where Dr. Jon Miller performed a surgical procedure: the decompression L4-5 and L5-S1, the transforaminal lumbar interbody fusion L4-L5 and L5-S1, the placement of interbody cages, the posterior instrumentation L4-5 and L5-S1, and the grafting with cancellous allograft supplemented with bone morphogenic protein. Plaintiff PATRICIA SHEPARD later returned home, but her pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this cervical and lumbar fusion surgery, Plaintiff PATRICIA SHEPARD now suffers from severe injuries and damages including chronic pain syndrome, back pain, neck pain, anxiety, and narcotic dependence from prescribed painkillers. December 2012 was the first time that Plaintiff PATRICIA SHEPARD had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff PATRICIA SHEPARD did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until December 2012 at the earliest.

53. Plaintiff ROSEMARY PENTON is an adult individual who at all times relevant hereto was residing in the State of Alabama. On September 18, 2008, Plaintiff ROSEMARY PENTON presented at North Florida Surgery Center, where Dr. Robert Sackheim performed a surgical procedure: the lumbar discograghy at L3-L4, L4-L5, and L5-S1, utilizing INFUSE™ and the LT-cage in an off label manner. On June 10, 2009, Plaintiff ROSEMARY PENTON presented at Sacred Heart Hospital, where Dr. Charles Wolff performed a surgical procedure: the retroperitoneal approach for L5-S1 anterior lumbar interbody fusion, the bilateral discectomy at L5-S1, the placement of intervertebral body device, synthes PEEK cage with bone morphogenic protein in the interspace of L5-S1, the anterior column arthrodesis at L5-S1, and the anterior lumbar plating, placement of anterior lumbar locking plate at L5-S1. Plaintiff ROSEMARY

PENTON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff ROSEMARY PENTON now suffers from severe injuries and damages including chronic pain syndrome, back pain, herniated bulging discs, allergic reaction, bulging discs, musuloskeletal injury, and narcotic dependence from prescribed painkillers. January 2013 was the first time that Plaintiff ROSEMARY PENTON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff ROSEMARY PENTON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until January 2013 at the earliest.

54. Plaintiff RICHARD PLUMMER is an adult individual who at all times relevant hereto was residing in the State of California. On May 3, 2010, Plaintiff RICHARD PLUMMER presented at Presbyterian Intercommunity Hospital, where Dr. Christopher Aho performed a surgical procedure: the C5-6 radical cervical discectomy, the C5-6 application of biomechanical intervertebral device, the morcellized allograft and autograft for spine surgery. On August 6, 2010, Plaintiff RICHARD PULMMER presented at Presbyterian Intercommunity Hospital, where Dr. Christopher Aho performed a surgical procedure: the C3-7 posterolateral arthrodesis and fusion, the C3-7 laminectomy with bilateral foraminotomies, and the morcellized allograft and autograft for spine surgery, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff RICHARD PLUMMER later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff RICHARD PLUMMER now suffers from severe injuries and damages including chronic pain syndrome, back pain, shoulder pain, infection in the neck, deterioration, and narcotic dependence from prescribed painkillers. March 2012 was the first time that Plaintiff

RICHARD PLUMMER had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff RICHARD PLUMMER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until March 2012 at the earliest.

55. Plaintiff NICHOLAS SCHULTZ is an adult individual who at all times relevant hereto was residing in the State of Wisconsin. On July 15, 2003, Plaintiff NICHOLAS SCHULTZ presented at Columbia Hospital, where Dr. James Stoll performed a surgical procedure: the anterior L4-5 and vertebral resection, the anterior L4-5 and L5-S1 interbody fusion utilizing INFUSE and anterior LT cages(4), and the posterior L4 to S1 fusion with posterior L4 to S1 internal fixation. Plaintiff NICHOLAS SCHULTZ later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff NICHOLAS SCHULTZ now suffers from severe injuries and damages including chronic pain syndrome, back pain, leg pain, anxiety, and narcotic dependence from prescribed painkillers. January 2012 was the first time that Plaintiff NICHOLAS SCHULTZ had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff NICHOLAS SCHULTZ did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until January 2012 at the earliest.

56. Plaintiff MARY TIMMONS is an adult individual who at all times relevant hereto was residing in the State of California. On July 9, 2004, Plaintiff MARY TIMMONS presented at Santa Barbara Cottage Hospital, where Dr. E. Scott Conner performed a surgical procedure: the anterior cervical discectomy and fusion with partial microsurgical vertebreotomy at C5-C6 and C6-C7 utilizing segmental fixation, utilizing INFUSE™ and the LT-cage in an off label

manner. On July 16, 2004, Plaintiff MARY TIMMONS presented at Santa Barbara Cottage Hospital, where Dr. E. Scott Conner performed a surgical procedure: the re-exploration of anterior cervical wound, evacuation of prevertebral hematoma, placement of Jackson-Pratt drain. On February 2, 2005, Plaintiff MARY TIMMONS presented at Santa Barbara Cottage Hospital, where Dr. E. Scott Conner performed a surgical procedure: the exploration of cervical spinal fusion with removal of hardware. Plaintiff MARY TIMMONS later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff MARY TIMMONS now suffers from severe injuries and damages including chronic pain syndrome, neck pain, herniated bulging discs, allergic reaction, bulging discs, obstruction of airway, anxiety, and narcotic dependence from prescribed painkillers. February 2012 was the first time that Plaintiff MARY TIMMONS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MARY TIMMONS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2012 at the earliest.

57. Plaintiff MELODIE WARD is an adult individual who at all times relevant hereto was residing in the State of Wisconsin. On May 27, 2009, Plaintiff MELODIE WARD presented at ST Mary's Hospital, where Dr. Alan Lozier performed a surgical procedure: the C4-5 anterior cervical discectomy and arthrodesis with structural allograft and anterior instrumentation using the operating microscope, utilizing INFUSE™ and the LT-cage in an off label manner.. Plaintiff MELODIE WARD later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff MELODIE WARD now suffers from severe injuries and damages including chronic pain syndrome, neck pain, suboccipital headaches, and narcotic dependence from prescribed painkillers. August 2012

was the first time that Plaintiff MELODIE WARD had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MELODIE WARD did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until August 2012 at the earliest.

58. Plaintiff CYNTHIA GIBSON is an adult individual who at all times relevant hereto was residing in the State of Tennessee. On June 12, 2002, Plaintiff CYNTHIA GIBSON presented at Jackson Madison County general Hospital, where Dr. Glenn Barnett performed a surgical procedure: the anterior cervical discectomy and allograft fusion of C5-6 with plating of C5 to C67. On January 8, 2003, Plaintiff CYNTHIA GIBSON presented at Jackson Madison County general Hospital, where Dr. J. Michael Glover performed a surgical procedure: the posterior cervical fusion with C5 to C6 and the removal of anterior cervical plate, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff CYNTHIA GIBSON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff CYNTHIA GIBSON now suffers from severe injuries and damages including chronic pain syndrome, neck pain, herniated bulging discs, bulging discs, obstruction of airway, and narcotic dependence from prescribed painkillers. March 2013 was the first time that Plaintiff CYNTHIA GIBSON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff CYNTHIA GIBSON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until March 2013 at the earliest.

59. Plaintiff SHEILA GOODMAN-GILBERT is an adult individual who at all times relevant hereto was residing in the State of Oklahoma. On July 16, 2009, Plaintiff SHEILA GOODMAN-GILBERT presented at Hillcrest Medical Center, where Dr. John Main performed

a surgical procedure: the C4-C5, C5-C6, C6-C7 anterior cervical discectomy and fusion with placement of stryker PEEK interbody cage at C4-C7, placement of stryker reflex hybrid plate, genex with morcellized autograft for fusion material. Plaintiff SHEILA GOODMAN-GILBERT later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff SHEILA GOODMAN-GILBERT now suffers from severe injuries and damages. September 2012 was the first time that Plaintiff SHEILA GOODMAN-GILBERT had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHEILA GOODMAN-GILBERT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until September 2012 at the earliest.

60. Plaintiff KRISTAL REED is an adult individual who at all times relevant hereto was residing in the State of Alabama. On May 16, 2006, Plaintiff KRISTAL REED presented at Brookwood Medical Center, where Dr. Charlie Talbert performed a surgical procedure: the lumbar fusion at L5-S1, the bilateral lateral transverse process fusion with pedicle screws at L5 and S1, utilizing INFUSE™ and the LT-cage in an off label manner. On April 9, 2009, Plaintiff KRISTAL REED presented at ST. Vincent's Hospital, where Dr. E. Carter Morris performed a surgical procedure: the removal of lumbar pedicle screws and hardware. Plaintiff KRISTAL REED later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff KRISTAL REED now suffers from severe injuries and damages including chronic pain syndrome, back pain, leg pain, lumbar postlaminectomy syndrome, lumbar degenerative disc disease, lumbar radiculopathy, sacroiliac pain, and narcotic dependence from prescribed painkillers. April 2013 was the first time that Plaintiff KRISTAL REED had reason to suspect that INFUSE™ caused

her symptoms. Thus, Plaintiff KRISTAL REED did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2013 at the earliest.

61. Plaintiff PENNY ROMERO is an adult individual who at all times relevant hereto was residing in the State of California. On January 29, 2008, Plaintiff PENNY ROMERO presented at Citrus Valley Medical Center, where Dr. Scott Lederhaus performed a surgical procedure: the anterior C6-7 diskectomy with plating using the zimmer plate screws and allograft bone fusion with microscopic dissection and intraoperative fluoroscopy. On December 1, 2008, Plaintiff PENNY ROMERO presented at St. Bernardine Medical Center, where Dr. Darren Bergey performed a surgical procedure: the L4-5, L5-S1 anterior lumbar discectomy and fusion using active-fuse and end-fuse, the placement of intervertebral cage at L4-5, L5-S1 using a zuma feet cage, and the anterior instrumentation at L4-5, L5-S1 using a zuma instrument, anterior plate and screws, thus utilizing INFUSE™ and the LT-cage in an off label manner. On December 4, 2008, Plaintiff PENNY ROMERO presented at St. Bernardine Medical Center, where Dr. Darren Bergey performed a surgical procedure: the L3, L4, L5 laminectomy, the L2 and S1 bilateral laminotomy for decompression of the L4, L5, S1 nerve roots, and the fusion L4 through S1 using autograft an actifuse. Plaintiff PENNY ROMERO later returned home, but her pain and difficulties did not subside.As a direct and proximate result of the use of INFUSE™ in this lumbar and cervical fusion surgery, Plaintiff PENNY ROMERO now suffers from severe injuries and damages including chronic pain syndrome, arm pain, numbness, tingling, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff PENNY ROMERO had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff

PENNY ROMERO did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until May 2012 at the earliest.

62. Plaintiff SHIRLEY HANEY is an adult individual who at all times relevant hereto was residing in the State of Texas. On May 24, 1999, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center, where Dr. Robert Viere performed a surgical procedure: the anterior, complete disc excision, L4-5 and L5-S1 with partial endplate excision, the anterior lumbar interbody fusion at L4-5 and L5-S1, the redo TSRH segmental instrumentation with intrasacral fixation from T12 to S1, the redo posterior lateral fusion at T12, L1, L1-2, L4-5, and L5-S1, the removal of previous segmental instrumentation form T12 to S1, and the iliac crest bone graft, utilizing INFUSE™ and the LT-cage in an off label manner. On October 15, 1999, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center , where Dr. Robert Viere performed a surgical procedure: the redo laminectomy and foraminotomy at left side of L4-L5 and L5-S1. On December 6, 2005, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center, where Dr. Robert Viere performed a surgical procedure: the revision decompression L5-S1, interbody fusion, and exploration fusion. On October, 13, 2010, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center, where Dr. Robert Viere performed a surgical procedure. Plaintiff SHIRLEY HANEY later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff SHIRLEY HANEY now suffers from severe injuries and damages. October 2012 was the first time that Plaintiff SHIRLEY HANEY had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHIRLEY HANEY did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until October 2012 at the earliest.

63. Plaintiff KAREN SAPPINGTON is an adult individual who at all times relevant hereto was residing in the State of Illinois. On October 31, 2008, Plaintiff KAREN SAPPINGTON presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the C5-C6 and C6-C7 anterior cervical discectomy, the placement of interbody spacer C5-6 and C6-7 with anterior cervical fusion, the augmentation of anterior cervical fusion C5-6 and C6-7, utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff KAREN SAPPINGTON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff KAREN SAPPINGTON now suffers from severe injuries and damages including chronic pain syndrome, neck pain, bulging discs, and narcotic dependence from prescribed painkillers. February 2012 was the first time that Plaintiff KAREN SAPPINGTON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff KAREN SAPPINGTON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2012 at the earliest.

64. Plaintiff LINDA THOMPSON is an adult individual who at all times relevant hereto was residing in the State of Louisiana. On November 1, 2010, Plaintiff LINDA THOMPSON presented at Baton Rouge General Medical Center, where Dr. Gary Dennis performed a lumbar fusion surgery utilizing recombinant bone morphogenetic protein, thus utilizing INFUSE™ and the LT-cage in an off label manner. Plaintiff LINDA THOMPSON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff LINDA THOMPSON now suffers from severe injuries and damages including chronic pain syndrome, neck pain, and bulging discs. February 2013 was the first time that Plaintiff LINDA THOMPSON had reason to suspect that

INFUSE™ caused her symptoms. Thus, Plaintiff LINDA THOMPSON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2013 at the earliest.

65. Plaintiff SCOTT SMITH is an adult individual who at all times relevant hereto was residing in the State of Florida. On June 7, 2007, Plaintiff SCOTT SMITH presented at Baptist Medical Center South, where Dr. Graham Smith performed a surgical procedure: a right sacroliliac joint fusion with TSRH instrumentation, utilizing the LT-Cage and bone morphogenic protein. Subsequently, on October 11, 2007 a left sacroiliac joint fusion was performed by Dr. Smith, utilizing the LT-Cage and INFUSE. Plaintiff SCOTT SMITH later returned home, but his pain and difficulties did not subside. He subsequently needed two additional surgeries on February 25, 2008 to remove an ectopic calcification, and an additional surgery on December 15, 2008, to remove the bilateral sacroiliac joint LT cages. As a direct and proximate result of the use of INFUSE™ in this surgery, Plaintiff SCOTT SMITH now suffers from severe injuries and damages including chronic pain syndrome, neck pain, bulging discs, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff SCOTT SMITH had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff SCOTT SMITH did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injuries until May 2012 at the earliest.

DEFENDANTS

66. Defendant MEDTRONIC, INC. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Defendant MEDTRONIC, INC. is engaged in business in the State of California.

67. Defendant MEDTRONIC SOFAMOR DANEK USA, INC. ("MEDTRONIC SD") is a Tennessee corporation, with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132. Defendant MEDTRONIC, SOFAMOR DANEK USA, INC. is engaged in business in the state of California.

68. Defendant MEDTRONIC VERTELINK is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of California, with its principal place of business in Minneapolis, Minnesota. Defendant MEDTRONIC VERTELINK, INC. is engaged in business in the State of California.

69. Defendants MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., and MEDTRONIC VERTELINK, INC., collectively known as "Medtronic" are now, and at all times mentioned in this Complaint were, in the business of designing, manufacturing, constructing, assembling, inspecting and selling various types of medical drugs and devices, including spinal surgery drugs and devices, and specifically the Infuse Bone Graft and LT-Cage, collectively known as "Infuse."

70. Defendant WYETH INC. is and at all times herein mentioned was, a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Trenton, New Jersey. Defendant WYETH INC. is engaged in business in the State of California.

71. Defendant WYETH PHARMACEUTICALS, INC. is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of Pennsylvania, with its principal place of business in Harrisburg, Pennsylvania. Defendant WYETH PHARMACEUTICALS, INC. is engaged in business in the State of California.

72. Defendant PFIZER, INC. is, and all times herein mentioned was, a corporation organized and existing under the laws of the State of New York, and maintains offices and does business in the State of California. Defendant maintains distribution centers in California, that are responsible for processing customer orders for Medtronic's rhBMP-2 drug component of the Infuse Bone Graft.

73. Defendant DR. GARY K. MICHELSON is and at all times herein was a resident of Los Angeles, California, Dr. Gary Michelson was partially responsible for inventing, designing, promoting and marketing Medtronic's LT-Case component of INFUSE.

74. Defendants WYETH INC. and WYETH PHARMACEUTICALS, INC. are wholly-owned subsidiaries of PFIZER, INC., collectively known as "Wyeth" are now, and at all times mentioned in this Complaint, were, in the business of designing, manufacturing, constructing, assembling, inspecting, and selling various types of medical drugs and devices, specifically Medtronic's rhBMP-2 drug component of the Infuse Bone Graft.

51. Defendant DR. GARY K. MICHELSON is, and at all times herein mentioned was a resident of the county of Los Angeles in the state of California. Dr. Michelson was partly responsible for inventing, designing, promoting, and marketing Medtronic's LT-Cage component of Infuse.

75. MARAL AMIRI, is a resident of the State of California, and at all times pertinent was the Area Sales Manager of Neurologic Technologies at Medtronic in Los Angeles California, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, by creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products.

76. ALEX BOLANOS is a resident of the State of California, and all times pertinent was District Sales Manager at Medtronic Spine & Biologics in Los Angeles, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, and creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products, and managing a team of spine consultants to promote the off-label use of Infuse Bone Graft.

77. KEVIN BRADLEY is a resident of the State of California, and all times pertinent was Senior District Sales Manager at Medtronic Spine & Biologics in Los Angeles, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, and creating new referral channels and providing operating room technical support to

orthopedic surgeons and neurosurgeons who use such products, and managing a team of spine consultants to promote the off-label use of Infuse Bone Graft.

78. DEBBIE PAGACH is a resident of the State of California, and all times pertinent was District Sales Manager at Medtronic Spine & Biologics in Los Angeles, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, and creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products, and assisting hospitals throughout the Greater Los Angeles area to insure the availability of Infuse Bone Graft to individual health care providers who practice at these hospitals, and to in other ways promote the off-label use of Infuse Bone Graft.

79. Defendants Amiri, Bolanos, Bradley and Pagach, ("Defendant Medtronic Managers" or "all Defendants"), were and are in Medtronic upper management, and at all times pertinent, aware of, and did actively promote Infuse Bone Graft to various healthcare providers in the State of California, and other states, including those healthcare providers who were involved in the Plaintiffs' surgeries.

80. The true names and capacities, whether individual, corporate, associate, or otherwise, of the defendants named herein, under the fictitious names of DOES 1 through 100, inclusive, are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. Plaintiffs will ask leave of Court to amend this Complaint and insert the true names and capacities of said defendants when the same have been ascertained. Plaintiffs are informed and believe and based thereon allege that each of the defendants designated herein as "Doe" is legally responsible in some manner for the events and happenings herein alleged, and that Plaintiffs' damages were proximately caused by such defendants.

81. At all times herein mentioned, defendants, each of them, and their aggregates, corporates, associates, and partners, and each of them, were the agent, servant, employee, assignee, permissive user, successor in interest or joint venture of each other, and were acting within the time, purpose or scope of such agency or employment or permission; and all acts or

omissions alleged herein of each such defendant were authorized, adopted, approved, or ratified by each of the other defendants.

82. This court has personal jurisdiction over Defendants because at all relevant times they engaged in substantial business activities in the State of California, or in the alternative, were domiciled in the State of California. At all relevant times, Defendants Medtronic, Pfizer, and Wyeth transacted, solicited, and conducted business in California through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in California. Furthermore, Dr. Michelson is a resident of the county of Los Angeles, in the State of California. The Medtronic Managers are also residents of the State of California.

1) ALLEGATIONS

a) Generally.

82. At all relevant times, INFUSE™ was researched, developed, manufactured, marketed, promoted, advertised, sold and distributed by the MEDTRONIC Defendants.

83. Plaintiffs suffered grievous personal injuries as a direct and proximate result of Defendants' misconduct.

84. In off-label lumbar or cervical spine surgeries, and even other off-label surgeries, INFUSE™ often leads to serious complications including, but not limited to, chronic permanent radiculitis and other nerve injuries, uncontrolled bone growth, osteolysis, and poorer overall outcomes.

b) MEDTRONIC's Representations.

85. At all relevant times, the MEDTRONIC Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed INFUSE™ as a safe and effective device to be used for spinal fusion surgery. MEDTRONIC negligently, recklessly, and/or intentionally promoted INFUSE™ for off-label use to physicians and spine patients, including the Plaintiffs and Plaintiffs' physicians, and downplayed to physicians and spine patients its dangerous effects, including but not limited to the downplaying of the dangerous effects of INFUSE™ in off-label spine surgeries such as that performed on the Plaintiffs.

86. At all relevant times, the MEDTRONIC Defendants misrepresented the safety of INFUSE™ to physicians and patients, and recklessly, willfully, and/or intentionally failed to alert physicians and patients of the increased significant danger to patients resulting from the off-label uses of INFUSE™.

c) **MEDTRONIC's Knowledge.**

87. MEDTRONIC and its agents knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to spine surgeons regarding INFUSE™ and including MEDTRONIC's surreptitious campaign to promote the product for off-label uses (i.e. uses that had never been evaluated or approved by the FDA). The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of personnel at the highest level of MEDTRONIC, including its corporate officers.

88. At all relevant times, MEDTRONIC knew, and/or had reason to know, that INFUSE™ was not safe for off-label uses in the spine because the device had never been approved for use in the spine, other than solely in anterior approach lumbar fusion surgeries with a LT-Cage™; and its safety and efficacy for use without a LT-Cage™ was known by MEDTRONIC to be unsafe and ineffective.

89. At all relevant times, MEDTRONIC knew, and/or had reason to know that INFUSE™ was not safe for off-label use because it had not been approved for off-label use; and its safety and efficacy for off-label use was either unknown, or was known by MEDTRONIC to be unsafe and ineffective.

90. MEDTRONIC's acts to promote off-label use of INFUSE™, their knowledge of, but failure to disclose, the growing adverse events associated with the product, MEDTRONIC's continued payments to certain spine surgeon "Opinion Leaders" to promote off-label uses, repeat FDA regulatory action against MEDTRONIC, two whistleblower lawsuits against MEDTRONIC, a Department of Justice ("DOJ") settlement and resulting Corporate Integrity

Agreement, and a United States Senate Finance Committee investigation culminating in a scathing report on MEDTRONIC's improper promotional activities on this product demonstrate a conscious and reckless disregard for the health and safety of spinal patients, including Plaintiff.

91. At all relevant times, the MEDTRONIC Defendants knew, and/or had reason to know, that their representations and suggestions to physicians that INFUSE™ was safe and effective for off-label use were materially false and misleading and that physicians and patients would rely on such representations.

92. MEDTRONIC knew and/or had reason to know of the likelihood of serious injuries caused by the off-label use of INFUSE™ in the spine, but they concealed this information and did not warn Plaintiffs or Plaintiffs' physicians, preventing Plaintiffs and Plaintiffs' physicians from making informed choices in selecting other treatments or therapies prior to Plaintiffs' implantation surgery and preventing Plaintiffs and their physicians from timely discovering Plaintiffs' injuries.

93. The prevailing best scientific and medical knowledge, as discussed *supra*, demonstrated prior to the date of Plaintiffs' injury that off-label INFUSE™ was likely to cause the Plaintiffs' injuries as stated herein. This prevailing scientific and medical knowledge was known or knowable by MEDTRONIC for at least a year or more prior to Plaintiffs' off-label INFUSE™ surgery.

d) MEDTRONIC's Off-Label Promotion.

94. MEDTRONIC had knowledge and information reflecting the true risks and dangers to spine patients of off-label use of INFUSE™, the extent of the off-label use, and their reckless promotion of the off-label uses. Despite this knowledge, MEDTRONIC knowingly and recklessly conducted an egregious off-label promotion campaign to the detriment of the spine patients, including the Plaintiffs.

95. MEDTRONIC and its agents encouraged the off-label promotion of INFUSE™ described throughout this Complaint, notwithstanding their knowledge of the serious adverse

events that patients could, and did, suffer, which have often resulted in the need for additional surgery, emergency intervention, and, in at least one case, the death of a patient.

96. The MEDTRONIC Defendants improperly promoted and marketed INFUSE™ to Plaintiffs' implanting surgeon for off-label use in the spine, and this improper promotion and marketing improperly influenced Plaintiffs' spine surgeon's decision to implant INFUSE™ in Plaintiffs' spine using an off-label approach.

97. The MEDTRONIC Defendants, as herein described, directly and indirectly promoted, trained, and encouraged Plaintiffs' surgeon to perform Plaintiffs' spinal fusion procedure utilizing INFUSE™ in a dangerous off-label manner.

98. The MEDTRONIC Defendants recklessly and/or fraudulently promoted and marketed INFUSE™ to Plaintiffs and Plaintiffs' physicians for off-label use in the spine.

e) Failure to Warn.

99. At all relevant times, the MEDTRONIC Defendants misrepresented the safety of INFUSE™ to physicians and spine patients, including to Plaintiffs and Plaintiffs' physicians, and recklessly, willfully, or intentionally failed to inform Plaintiffs or Plaintiffs' physicians of the significant dangers to patients resulting from the off-label use of INFUSE™.

100. Any warnings MEDTRONIC may have issued concerning the dangers of off-label uses of INFUSE™ or regarding the specific risks of those uses were insufficient in light of MEDTRONIC's contradictory prior, contemporaneous and continuing illegal promotional efforts and promotion of INFUSE™ for non-FDA-approved off-label uses in the spine and contemporaneous efforts to hide or downplay the true risks and dangers of the off-label uses of INFUSE™.

e) Causation.

101. Plaintiffs would not have consented to be treated with the off-label use of INFUSE™ had she known of or been informed by MEDTRONIC or by their spine surgeon of the true risks of the off-label use of INFUSE™.

102. Plaintiffs and Plaintiffs' spine surgeons relied on the MEDTRONIC Defendants' misrepresentations regarding the safety and efficacy of INFUSE™ in Plaintiffs' spine surgery. Plaintiffs and Plaintiffs' spine surgeon did not know of the specific risks, and/or were misled by the MEDTRONIC Defendants, who knew or should have known of the true risks but consciously chose not to inform Plaintiffs or their spine surgeon of those risks and to actively misrepresent those risks to the Plaintiffs and Plaintiffs' physician.

103. The MEDTRONIC Defendants' off-label promotion and marketing caused Plaintiffs' spine surgeons to decide to implant INFUSE™ in Plaintiffs' spine using an off-label approach.

104. Plaintiffs' spine surgeon received and relied on the MEDTRONIC Defendants' improper promotion of the off-label uses, and MEDTRONIC'S inadequate warnings which hid or downplayed the risks of off-label use of INFUSE™. Plaintiffs' spine surgeon would not have done the procedure using off-label INFUSE™ (or using INFUSE™ at all) in the absence of MEDTRONIC's false and misleading promotion of the off-label uses.

f) Alter Ego.

105. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiffs.

106. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified those actions.

107. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between certain Defendants and other certain Defendants, such that any individuality

and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

108. At all times herein mentioned, the MEDTRONIC Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiffs and Plaintiffs' physicians. As such, each of the MEDTRONIC Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

109. The harm which has been caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of the Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or which combination of the Defendants caused Plaintiffs' injuries.

110. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiffs.

2) <u>The INFUSE™ Device and Spinal Fusion Surgery Generally.</u>

111. MEDTRONIC designed and marketed INFUSE™ for lumbar spine fusion surgery, a surgical technique in which one or more of the vertebrae of the spine are united together ("fused") so that motion no longer occurs between them.

112. Spinal fusion is used to treat a number of conditions, including treatment of a fractured vertebra, spinal deformities (spinal curves or slippages), back pain from instability, or abnormal or excessive movement between vertebrae. Similar to the concept of welding, spinal

fusion surgery uses bone grafts to join vertebrae together and eliminate or reduce movement between vertebrae.

113. In a spinal fusion procedure, the graft — usually the patient's own harvested bone (autograft) or cadaver bone (allograft) — is placed in a spacer cage within the disc space between the vertebrae during the surgery. Over the following months, a physiological mechanism similar to that which occurs when a fractured bone heals causes the graft to join, or "weld," the vertebrae together. The goal of spinal fusion is to obtain a solid fusion of the vertebrae.

114. For years, autologous bone graft has been considered the "gold standard" in fusion surgery. In an autologous bone graft — or "autograft" — the surgeon procures bone graft material from another part of the patient's body, typically from the patient's pelvis or iliac crest or from the patient's own spine (from the parts of one or more vertebrae removed to gain access to the disc space to perform the fusion), and implants the bone graft in the site where fusion is desired. Successful fusions occur at very high rates in autograft procedures, as the harvested bone exhibits all the properties necessary for bone growth (including osteogenic, osteoconductive and osteoinductive properties).

115. As an alternative to autograft, patients can undergo an "allograft" procedure using cadaver bone instead of autograft. Although healing and fusion is not as predictable when using allograft as when using autograft (the patient's own bone), an allograft eliminates the need for the harvest procedure required in an autograft.

116. A newer option to traditional bone graft procedures is bio-engineered and bio-manufactured bone-growth materials, including INFUSE™. INFUSE™ and similar materials were thus (at least initially) appealing to many spine surgeons, since they can obviate the need for using autograft harvested from the patient's own body.

117. INFUSE™ is a genetically engineered material containing a bone morphogenetic protein ("rhBMP-2"), and is used as an alternative or supplement to autograft and allograft to help fuse the vertebrae in the spine as part of the spinal fusion surgery. The purpose of

INFUSE™ is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the need to harvest bone from the patient's hip or spine.

118. MEDTRONIC'S INFUSE™ product consists of (1) a metallic spinal fusion cage (the LT-Cage™); (2) the bone graft substitute which consists of liquid rhBMP-2 (derived from Chinese hamster cells); and (3) a sponge-like carrier or scaffold for the protein (manufactured from bovine collagen) that is placed inside the fusion cage (LT-Cage).

119. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the INFUSE™ bone graft component is used to form bone, which is intended to permanently stabilize (fuse) this portion of the spine.

120. During surgery, the rhBMP-2 is soaked onto and is intended to bind with the absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge dissolves, the rhBMP-2 stimulates the cells to produce new bone.

121. Certain bone morphogenetic proteins ("BMP"s) have been studied for decades because of their ability to heal bone and potentially decrease or eliminate the need for bone graft harvesting from other parts of the body.

122. Scientists isolated the gene for one protein (rhBMP-2) from bone tissue and used molecular biology techniques to create genetically engineered cells. These cells then produce large quantities of rhBMP-2. A similar process is used to manufacture other proteins, such as insulin.

123. Attempting to seize on this potentially lucrative opportunity to develop a new spinal fusion method, Sofamor Danek Group, Inc., a Memphis, Tennessee-based spinal device maker ("Sofamor Danek"), acquired the exclusive rights to rhBMP-2 for spinal applications in February 1995. The "rhBMP-2" liquid bone protein sold as INFUSE™ is a genetically engineered version of a naturally occurring protein that stimulates bone growth, developed as a commercially viable bone morphogenetic protein ("BMP") technology.

124. In October 1996, Sofamor Danek filed with the FDA an application for an Investigational Device Exemption to conduct a pilot study on the effects of rhBMP-2 in humans, marking the first step to obtaining approval to commercially market BMP.

125. In January 1999, MEDTRONIC purchased Sofamor Danek for $3.6 billion. On July 2, 2002, the FDA approved INFUSE™, a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, for one limited and very specific spinal fusion procedure.

126. Today, INFUSE in its entirety is a combination product, composed of a device and biologic. Infuse is a combination product because the sponge is soaked in rhBMP-2 solution and sterile water, and placed within a metal cage that acts as a place-holding scaffold. The rhBMP-2 protein promotes the new bone growth to fuse the spine, and completes the spinal fusion process.

127. The metal cage is manufactured by Medtronic in accordance with the Medical Device Quality System Regulation. The sponge is manufactured by a vendor for Medtronic, also under the Medical Device Quality System Regulation. Meanwhile, the rhBMP-2 protein is manufactured by Wyeth and Pfizer for Medtronic, in accordance with the Center for Biologics Evaluation and Research. The sterile water is produced by a supplier in compliance with the CGMP for pharmaceuticals.

3) FDA Approval of INFUSE™.

a) The Pre-Market-Approval Process.

128. The current regulatory framework for medical device approval was established in the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated

external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. INFUSE™ is a Class III device.

129. Manufacturers such as the MEDTRONIC Defendants seeking to market Class III devices, such as INFUSE™, are required to submit a Premarket Approval Application ("PMA") that must be evaluated and approved by the FDA. The PMA requires the manufacturer to demonstrate the product's safety and efficacy to the FDA through a process that analyzes clinical and other data, including: (1) technical data and information on the product, including non-clinical laboratory studies and clinical investigations; (2) non-clinical laboratory studies that provide information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests of the device—all of which must be conducted in compliance with federal regulations which set forth, *inter alia*, criteria for researcher qualifications, facility standards and testing procedures; and (3) clinical investigations in which study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations are provided, including the results of any investigation conducted under an Investigational Device Exemption ("IDE").

130. A PMA requires that all pertinent information about the device be articulated in the application and requires the manufacturer to specify the medical device's "intended use." The indications for use required on the label are based on the nonclinical and clinical studies described in the PMA. Indications for use for a device include a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

131. In addition, each PMA submission must include copies of all proposed labeling for the device, which must comply with federal requirements. Specifically, the label must include the common name of the device, quantity of contents, and the name and address of the manufacturer, as well as any prescription use restrictions, information for use (including

indications, effects, routes, methods, and frequency and duration of administration; and any relevant hazards, contraindications, side effects, and precautions), instructions for installation and operation, and any other information, literature, or advertising that constitutes "labeling" under the FDCA. Approval of the product's labeling is conditioned on the applicant incorporating any labeling changes exactly as directed by the FDA, and a copy of the final printed labeling must be submitted to the FDA before marketing.

b) **INFUSE's™ Limited FDA-Approved Uses.**

132. In October 1996, Sofamor Danek submitted an IDE to the FDA to study the use of rhBMP-2 as applied to an absorbable collagen sponge inserted into an LT-Cage™ interbody fusion device to treat patients with degenerative disc disease. Designed as a pilot study intended to support the initiation of a larger pivotal study, the IDE involved 14 patients—11 of whom received spinal fusion procedures using the rhBMP-2/ACS/LT-Cage™ device and 3 who received the LT-Cage™ with autologous bone—and marked the first time rhBMP-2 was used in patients undergoing spinal fusion. In this initial clinical trial, all 11 patients who had been implanted with rhBMP-2 achieved successful fusion within six months from the time of surgery.

133. Sofamor Danek used the results of this pilot study to petition the FDA to initiate a pivotal trial of rhBMP-2 with the LT-Cage™®. This trial, which was approved by the FDA in July 1998, involved 135 investigational patients who had rhBMP-2 implanted in a single-level Anterior Lumbar Interbody Fusion (ALIF) procedure and 135 control patients who underwent the same procedure using autologous bone graft instead of rhBMP-2.

134. After acquiring Sofamor Danek in 1999, MEDTRONIC filed the INFUSE™ PMA on January 12, 2001, and was granted expedited review status by the FDA.

135. As presented in MEDTRONIC's original PMA (eventually approved by the FDA in July 2002), the initially-approved INFUSE™ product consisted of two components:

a. A specific type of spacer (the LT-Cage™ Lumbar Tapered Fusion Device) component, which is a thimble-sized hollow metal cylinder which keeps the two

vertebrae in place and provides a frame that contains and directs the development of new bone growth; and

b. The INFUSE™ Bone Graft Component, which includes a collagen sponge that acts as a carrier and scaffold for the active ingredient in INFUSE™, and rhBMP-2, the actual active ingredient that is reconstituted in sterile water and applied to the collagen sponge before it is placed inside the spacer cage.

134. According to the label sought by MEDTRONIC in the PMA and subsequently approved by the FDA, INFUSE™ can only be used in an ALIF procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine.[1] ALIF is performed by approaching the spine from the front through an incision in the abdomen.

135. On July 2, 2002, the FDA approved INFUSE™ to treat degenerative disc disease, but only by means of one specific procedure, namely, the ALIF procedure, and only in one-level procedures at lumbar spine levels L4 through S1.

136. Importantly, the initial approved labeling for the product indicates in bold underlined formatting: **"These components must be used as a system. The INFUSE™ Bone Graft component must not be used without the LT-Cage™ Lumbar Tapered Fusion Device component."** The labeling also directs the specific manner in which both components are to be used in a fusion procedure. Thus, the LT-Cage Lumbar tapered fusion device component, a thimble-sized metal cylinder that keeps the vertebrate in place and is intended to provide a frame for new boned growth, must be utilized with the INFUSE component and its absorbable collagen sponge.

[1] While the product's label remains substantially the same as that approved by the FDA in 2002, the FDA has made minor amendments to the label through post-approval supplements. For example, on July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1. InFUSE™ has been approved by the FDA for only two other uses: certain oral maxillofacial surgeries and repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management. InFUSE™ was approved by the FDA on March 9, 2007, for certain oral maxillofacial uses. While InFUSE™ has also been approved for treatment of certain tibial fractures and certain oral maxillofacial uses, these uses represent a very minor percentage of the product's overall sales.

137. Despite the fact that the FDA only approved rhBMP-2 for use in the spine in combination with use of the LT-Cage™, MEDTRONIC sells INFUSE™ separately from the LT-Cage™, and has done so continuously since the approval in 2002. Nonetheless, no surgery takes place without the LT-Cage™.

138. INFUSE™ has never been approved by the FDA for use in other parts of the body or for use in any other type of procedure, other than two non-spinal uses as noted in footnote 1. Any other uses are thus, by definition, "off-label" experimental uses which are not approved by the FDA.

139. There are numerous lumbar and cervical spine surgical procedures for which INFUSE™ was not initially approved, and for which it has never subsequently been approved. No cervical fusion procedure, whatsoever, using INFUSE™ has ever been approved by FDA, regardless of the approach or procedure. The non-approved lumbar procedures include:

c. Posterior Lumbar Interbody Fusion ("PLIF"), a procedure that is used to treat nerve compression, and back pain resulting from a number of causes, involves approaching the spine from the back. PLIF, however, is a more delicate surgical approach in some respects because the spinal canal and nerves are posterior to the vertebral body, and because a surgeon must manipulate the dural sac (the membranous sac that encases the spinal cord within the vertebral column) to perform the PLIF procedure;

d. Posterolateral Fusion ("PLF") which is similar to the PLIF procedure, but instead of removing the disc space and replacing it with a bone graft, the disc space remains intact and the bone graft is placed between the transverse processes in the back of the spine. This allows the bone to heal and stabilizes the spine by fusing the transverse process of one vertebra to the transverse process of the next vertebra; and

e. Transforaminal Lumbar Interbody Fusion ("TLIF"), which is also similar to the PLIF procedure, and is a technique utilized when an inter-body fusion is performed via a posterior approach. TLIF allows the surgeon to perform a fusion from a posterior

approach without disturbing the dural sac by approaching the spine via a more lateral, or sideways, approach.

4) **Off-Label Use of INFUSE™, Risks Associated with Off-Label Uses, and MEDTRONIC's Knowledge of Such Risks.**

a) **Generally**

140. Physicians may use FDA-approved medical devices in any way they see fit — either on-label or off-label, but medical device companies are prohibited by federal law to promote off-label uses for their medical devices or to pay doctors inducements or kickbacks to promote off-label uses, or to perform procedures using the devices off-label. When a physician chooses to use a medical device in an off-label manner, he or she must inform the patient of the off-label nature of the surgery and the expected risks and benefits of such off-label use, and obtain the patient's informed consent to such use.

b) **FDA's Initial Concerns with INFUSE's™ Off-Label Uses.**

141. The FDA's approval of INFUSE™ was limited to one specific lumbar procedure (the ALIF procedure) due to FDA's concerns about potential adverse events in posterior uses that had already been reported at the time of the product's approval. As a result, the FDA approved INFUSE™ for the small percentage of overall spinal fusion surgeries which are ALIF procedures, with the device label specifying this limited surgical application.

142. FDA approval of INFUSE™ was limited to ALIF only because of the number of adverse events resulting from the use of rhBMP-2 in off-label applications. In particular, a MEDTRONIC-sponsored trial examining the application of rhBMP-2 in off-label PLIF (Posterior Lumbar Interbody Fixation) procedures was halted in December 1999 when uncontrolled bone growth developed in a number of the patients. Indeed, the study reported that one patient required two additional surgeries to remove excessive bone growth from the spinal canal. Such bone overgrowth observed in this PLIF trial was particularly alarming because it could, and did in many patients, result in worsening the very pain that the fusion procedure was

designed to eliminate, and in some cases necessitating difficult revision surgeries to remove the bone overgrowth.

143. Moreover, the 1999 PLIF trial demonstrated that bone overgrowth complications from INFUSE™ result from the product's very mechanism of action; i.e., rhBMP-2 stimulates the growth of new bone. Thus adverse events can result when the rhBMP-2 leaks out of the area in which bone growth is desired and/or when too much rhBMP-2 is used. In such cases, INFUSE™ can stimulate bone growth where new bone is not desired or can lead to excessive bone growth in the target area, which is often associated with other complications such as swelling, compression of nerves, and associated additional or new pain. Such unintended bone growth and swelling can be especially problematic in spinal surgeries because of the proximity to sensitive neurological structures in which INFUSE™ is used; i.e., the spinal cord and the exiting nerve roots.

144. During the FDA Advisory Committee Panel ("FDA Panel") hearing on January 10, 2002 concerning potential FDA approval of INFUSE™, Panel members voiced concerns regarding potential off-label use of the product, and asked MEDTRONIC to describe its efforts to guard against off-label use of the product.

145. In response to FDA concerns of off-label applications, one MEDTRONIC consultant, who is alleged to have received hundreds of thousands of dollars in the form of kickbacks from consulting agreements promoting INFUSE™, dismissed the FDA Panel's concerns of off-label use, stating: "this specific application before the panel today is through an anterior approach," and thus, "seems to me to be outside the scope of what we ought to be focusing on today."

146. Reiterating its concerns on off-label use, the FDA Panel cautioned MEDTRONIC to guard against procedures outside the specifically approved ALIF procedure provided in the labeled application. The FDA Panel's admonishment included concerns voiced by panel member Dr. John Kirkpatrick that off- label use could result in harm to patients. More specifically, the use of the ***tapered*** LT-Cage™ — which is difficult to implant in a posterior approach—would, if

required, "prevent a majority of surgeons from applying this from a Posterior Lumbar Interbody Fusion [PLIF] perspective." In other words, the FDA explicitly warned MEDTRONIC against promoting INFUSE™ for use in off- label PLIF procedures because, according to the statements of the FDA Panel, such use could endanger patients.

147. At this 2002 FDA Advisory Committee Panel hearing, the panel members stressed concerns regarding potential off-label use of the product and repeatedly asked the MEDTRONIC presenters questions about how MEDTRONIC would seek to guard against off-label applications of the product.

148. At the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing the MEDTRONIC Defendants to guard against procedures other than the specific ALIF (anterior lumbar interbody fusion) procedure approved by the FDA.

c) Off-Label Use of INFUSE™ is Dangerous and Causes Adverse Side Effects.

149. The off-label use of INFUSE™ in the spine frequently causes serious adverse events. This has been known to MEDTRONIC and its key "opinion leaders" for many years.

150. The FDA Panel's initial fears in 2002 concerning the dangers of off-label use of this product were confirmed by subsequent medical studies that demonstrate that off-label use of INFUSE™ may present severe risks and dangers to patient safety.

151. For example, an early study sponsored and funded by MEDTRONIC in 1999 demonstrated an approximately 70% rate of ectopic bone growth — meaning bone overgrowth where such growth is not desired. Only a few months into this clinical trial of INFUSE™, CT scans showed unwanted bone had formed in the spinal canals of 70% of the patients treated with INFUSE™. This clinical trial, intended to include hundreds of people with degenerative disc disease, was halted after only 34 patients were treated with INFUSE™.

152. A spine surgeon who participated in this PLIF with INFUSE™ study reported that one of the patients he treated required two extra surgeries to clear the excessive bone growth

from the patient's spinal canal. The complications observed in this PLIF trial were particularly serious given the potential of neural impingement (or nerve pinching) from such bony overgrowth in that procedure, potentially triggering the very sort of pain that a fusion procedure attempts to eliminate.

153. This bone overgrowth results from INFUSE™'s very mechanism of action. In such cases, INFUSE™ can stimulate bone growth where new bone is not desired and can lead to excessive bone growth into areas where bone should not be growing — *i.e.*, into or against the spinal cord or other spinal nerves.

154. There is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in the off-label procedures such as PLIF, TLIF, PLF and cervical fusions, or the expected responses to the protein in different biological environments. Indeed, many adverse events associated with the use of INFUSE™ result from off-label use of the product by surgeons who do not fully understand the highly potent nature of this molecule.

155. A study entitled, "Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures," Cahill, et al., *JAMA*, 2009 Jul 1;302(1):58-66, analyzed the integration of BMP into spinal surgeries since 2002, and the association between its use and postoperative complications, length of hospital stays, and hospital charges. Significantly, the study determined that use of bone morphogenetic proteins is associated with a substantially higher rate of complications in anterior cervical fusion procedures, which has resulted in an approximate 41% increase in hospital charges for these procedures. Notably, the study only considered complications that occurred during postoperative inpatient hospitalization immediately following the surgical procedure, and did "not include delayed complications in the outpatient setting," such as hospital readmission-related complications.

156. Such a shortcoming likely resulted in a significant understatement of the extent of complications resulting from use of bone morphogenetic proteins because, as an FDA Public Health Notification regarding complications from use of BMP in the cervical spine indicated,

"[m]ost complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2." Indeed, acknowledging this fact, Dr. Kevin S. Cahill, who led the study, publicly commented, "ours is probably a bottom estimate."

157. Aside from potential understatement of complications, the study found that the rate of complications in anterior cervical fusions was 51.4% higher when using bone morphogenetic protein than in similar cases when bone morphogenetic protein was not used. These complications included increased rates of voice and swallowing-related problems, and swelling of the neck. The study's authors noted a "significantly greater" rate of complications when using bone morphogenetic proteins in these surgeries, even after considering and compensating for numerous other variables that could affect complications rates, such as age, sex, etc.

158. Astonishingly, it was not until 2004 that a paper about the disastrous 1999 PLIF trial by spine surgeons with financial ties to MEDTRONIC was finally published in a medical journal. This article inaccurately maintained that these patients were not harmed by INFUSE™. The paper (Haid, et al., *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages, The Spine Journal*, 4(5):527-538, September 2004) downplayed the bone overgrowth complications claiming that while it showed up on CT scans, patients did not suffer ill effects. This claim was false and misleading and further encouraged dangerous off-label uses of INFUSE™.

159. In fact, David Malone, M.D., a Tulsa, Oklahoma spine surgeon involved in this 1999 PLIF clinical trial with INFUSE™, told the *Milwaukee Journal Sentinel* that two of his patients had to undergo additional surgeries because the BMP-induced bone overgrowth was painfully impinging on their nerve roots. One of the patients, a man who was in his 50s at the time, needed three operations - one for the implant, a second to remove the unwanted bone formation, and then a third when the additional bone grew back yet again.[2]

[2] *See, e.g.*, "InFUSE™ Cited in Patients' Painful Bone Overgrowth: More Surgery Needed After Use, Surgeon Says," by John Fauber, *Milwaukee Journal Sentinel*, June 27, 2011.

160. "It was a pretty amazing biological response," Malone said in an interview. "It grew back even larger than the first time. It got to the point that secretaries in our clinic could look at X-rays and tell who got the BMP (INFUSE™) and who did not. You could see that much bone growth."[3]

161. A May 15, 2006 medical article in *Spine* entitled "Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue" observed, "rhBMP-2 may stimulate bone growth in areas in which bone is not desired, especially as the material 'leaks' into such spaces. . . . Although this phenomenon has not been thoroughly studied, it implies that the release of rhBMP-2 into the soft tissues stimulates a rapid, potentially life-threatening, inflammatory reaction." [4]

162. Again, in a November 2006 issue of *Spine*, several authors noted a significantly increased risk of swelling from off-label use of INFUSE™ in cervical spine fusions compared to traditional fusion surgeries. Of the 234 patients studied, 27.5% of those patients treated with INFUSE™ had significant swelling after the surgery, while only 3.6% of those patients not treated with INFUSE™ experienced such a complication. Further analysis demonstrated that "patients receiving rhBMP-2 were ***10.1 times more likely*** to have a swelling complication versus those who did not receive rhBMP-2." (Emphasis added.)[5]

163. A March 2007 article in *The Spine Journal* highlighted the severity of the complications associated with off-label use of INFUSE™. According to this article, five days after INFUSE™ was implanted off-label in a cervical spine fusion surgery, the implanted patient experienced serious swelling of the neck and difficulty swallowing which required emergency medical treatment such as an exploratory surgery and implantation of a breathing tube.[6]

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[3] *Id.*

[4] Patel, et al, *Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue, Spine*, 31(11): 1201-1206, May 2006.

[5] Smucker, et al., *Increased Swelling Complications Associated with Off-Label Usage of rhBMP-2 in the Anterior Cervical Spine, Spine*, 31(24): 2813-2819, November 2006.

[6] Perri, et al., *Adverse Swelling Associated with Use of rh-BMP-2 in Anterior Cervical Discectomy and Fusion: A Case Study, The Spine Journal*, 7(2): 235-239, March 2007.

164. A *European Spine Journal* article in August 2007 found that use of INFUSE™ in certain cervical spine fusions resulted in a statistically significant increase in the number of complications, including dysphagia (difficulty in swallowing) and swelling in the neck area. The authors determined that "[d]ysphagia was a common complication and it was significantly more frequent and more severe in patients in whom rhBMP-2 was used. Post-operative swelling . . . was significantly larger in the rhBMP-2 group." Of the patients evaluated, 85% of those treated with INFUSE™ reported difficulty swallowing after the surgery; a complication that was far less severe in those not treated with INFUSE™. Indeed, one patient required a feeding tube for six weeks after the surgery as a result of the complication. [7]

165. On July 1, 2008, the FDA issued a Public Health Notification to healthcare practitioners entitled "Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion" (the "FDA Notification"), which strongly warned medical professionals who used INFUSE™ and other BMP products of serious complications that had occurred from the off-label use of these products in the cervical spine.[8]

166. The FDA Notification stated that the agency had received numerous reports of complications from BMP use in the cervical spine that "were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking." The notification further stated that these complications had resulted in "the need for emergency medical intervention," which included "respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site." The FDA Notification concluded that "in light of the serious adverse events described above, FDA

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[7] Vaidya, et al., *Complications of Anterior Cervical Discectomy and Fusion Using Recombinant Human Bone Morphogenetic Protein-2, European Spine Journal,* 16(8): 1257-1265, March 2007.

[8] FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion, July 1, 2008, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm

recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies."

167. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "MEDTRONIC Product Linked to Surgery Problems."[9] This article noted both the complications resulting from the use of INFUSE™ in the cervical spine already disclosed in the FDA Notification and additional complications resulting from other off-label applications of the product, stating:

> The FDA's alert about INFUSE™ was specific to neck surgeries. But a review of FDA records and medical literature shows there have been scores of other cases in which serious complications arose after the product was used in other off-label situations. Many of these cases involve unwanted bone growth near nerves or in areas outside targeted fusion sites. That can lead to pain, repeat surgeries and, in some cases, emergency intervention.

The article further stated that at least three-quarters, or 75%, of the adverse events reported to the FDA involved off-label use of INFUSE™. Of course, this news had serious implications for MEDTRONIC because off-label use of INFUSE™ accounted for the majority of all INFUSE™ sales.

168. A September 2008 article in *The Spine Journal* also observed that the use of INFUSE™ in the cervical spine "has been associated with reports of serious adverse events.[10] Postoperative hematoma formation [a collection of blood outside the blood vessels, generally manifesting as bruises], prevertebral soft tissue swelling, [and] swallowing difficulty . . . are a few examples." Of the complications observed in this patient study group, 17% occurred in patients treated with traditional techniques, while 83% occurred in patients treated off-label with INFUSE™. The authors concluded that the "cervical spine has proven much less forgiving with the institution of rhBMP-2 use. Complications induced by . . . rhBMP-2 were clearly evident in our review."

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[9] "Medtronic Product Linked to Surgery Problems," by David Armstrong and Thomas M. Burton, *Wall Street Journal*, September 4, 2008.

[10] Jarosz, et al., *Complications of BMP Use in Cervical Spine Surgery, The Spine Journal*, 8(5): 23S-24S, September 2008.

169. On November 18, 2008, in connection with reporting MEDTRONIC's financial results for its 2009 second quarter (ended October 24, 2008), MEDTRONIC reported that revenue from its Spinal segment had, in fact, declined to $829 million for the quarter – down $30 million from the previous quarter. The decreased sales in the Spinal segment, clearly stemming from a significant decline in INFUSE™ sales, were a sharp deviation from MEDTRONIC's reports of repeated, double-digit, growth in the Spinal segment in previous quarters. Moreover, MEDTRONIC disclosed, for the first time, that it "recently received a subpoena from the Department of Justice looking into off-label use of INFUSE™."

170. Thereafter, MEDTRONIC continued to report lower sales of INFUSE™, which it admittedly linked to a public health notice from the FDA regarding off-label use of recombinant human bone morphogenetic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories, and a whistleblower lawsuit filed by two former MEDTRONIC employees against MEDTRONIC and a number of spine surgeons and distributors of the INFUSE™ bone graft.

171. The use of INFUSE™ in off-label procedures was further scrutinized in a study published in the July 1, 2009 issue of JAMA that documented the health risks associated with off-label use of INFUSE™ and, contrary to previous studies conducted by MEDTRONIC-funded physicians, cast doubt on the cost-effectiveness of the product.[11]

172. At least 1,200 reports of adverse events involving INFUSE™ have been made to the FDA from 2002 to 2011. In 2011, for example, 278 INFUSE™-related adverse events were reported; in 2010, 362 adverse events were reported; and in 2009, 244 adverse events were reported. The vast majority of these adverse event reports involve off-label use of INFUSE™.

[11] Cahill, et al., *Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures, JAMA*, 302(1): 58-66, July 2009.

173. In fact, in a 2012 article published in The Spine Journal, FDA researcher Emily Woo, M.P.H. concluded on-label use of INFUSE™ accounts for only a tiny percentage (0.5%) of adverse events. Off-label use of INFUSE™ accounts for 99.5% of adverse events.[12]

174. The number of INFUSE™-related adverse events is growing steadily over the years, and the proportion of off-label adverse events grows, as well, as a direct result of the MEDTRONIC Defendants' long-standing campaign of improper off-label promotion of the more dangerous off-label uses of INFUSE™ which were never approved by the FDA. The extent of these adverse events was, at all relevant times, hidden or downplayed by MEDTRONIC and its paid consultants.

d) MEDTRONIC's Prior Knowledge and Concealment of the Dangers of Off-Label INFUSE™ Uses.

175. Even at the time of FDA approval, MEDTRONIC and its senior management and its paid consultant "opinion leaders," were well aware of the concerns regarding off-label uses of INFUSE™ and the serious dangers to patients posed by those off-label uses.

176. Notwithstanding the original FDA Panel's well-founded concerns regarding off-label use, as well as the medical literature's corroboration of the same, both of which MEDTRONIC had knowledge, MEDTRONIC intentionally, negligently and recklessly concealed these dangers from the general public, including the Plaintiffs and Plaintiffs' physicians.

177. MEDTRONIC had actual knowledge of the Advisory Committee's concerns regarding off-label use of the product and the dangers posed by off-label use. Indeed, Defendants were on actual notice at this time of the Advisory Committee's warnings that MEDTRONIC should guard against off-label uses of this potent genetically-engineered liquid bone protein. Thus, even *prior* to FDA approval, Defendants were on actual notice of the dangers that off-label use of INFUSE™ posed to patients, such as the Plaintiff.

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[12] Emily Jane Woo, *Recombinant Human Bone Morphogenetic Protein 2: Adverse Events Reported to the Manufacturer and User Facility Device Experience Database, The Spine Journal,* 12(10): 894-899, October 2012.

178. Further, as described immediately *infra*, the MEDTRONIC-funded studies on INFUSE™ from 1999 to until at least 2007 failed to accurately describe the adverse effects that were observed in the earliest trials of INFUSE™, such as severe uncontrolled or ectopic bone growth, severe inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement. These MEDTRONIC-funded articles also omitted any mention of the risks of sterility and cancer associated with rhBMP-2 use, as reported in FDA documents and hearings. MEDTRONIC discouraged the publication of these results in the medical journal literature, thereby hiding significant side effects from spine surgeons and patients.

179. Further, Confidential Witness #2 ("CW 2") in a shareholder derivative lawsuit filed against MEDTRONIC, more fully discussed *supra*, stated that MEDTRONIC was aware of adverse events resulting from off-label use of INFUSE™ in the cervical spine, including swallowing, and breathing problems.

180. In response to these reports of adverse events, CW 2 stated that MEDTRONIC attempted to disseminate information to the medical community regarding what it considered to be the proper dose of INFUSE™ for this off-label application. MEDTRONIC also issued a "Safety Alert" letter to surgeons on September 14, 2004, informing them that MEDTRONIC had received reports of complications associated with off-label use of INFUSE™ in anterior cervical fusion procedures. MEDTRONIC wrote, "***[l]ocalized soft tissue edema has been reported in anterior cervical spine fusion surgery following the use of INFUSE™ Bone Graft…. Some reports were accompanied by patient complaints of swelling and difficulty in swallowing and breathing, three of which resulted in surgical intervention.***" (Emphasis added.)

181. These adverse events were not isolated incidents, as described above. These adverse event reports from off-label uses of INFUSE™ indicate the very same complications as those noted in the studies discussed above, including, swelling, difficulty swallowing and breathing, excessive bone growth resulting in dangerous and painful spinal nerve compression

and corresponding injuries, etc., and often require emergency medical intervention or a second surgery.

182. For example, a December 12, 2005 report indicates that four or five days after an off-label PLIF procedure using INFUSE™, the patient's swelling became so severe that surgical intervention was required.

183. A November 3, 2006 report indicates that a patient reported neck swelling, difficulty swallowing and possible shortness of breath two to three days after a cervical spine fusion using INFUSE™. As a result, this patient had to undergo another surgery four days after the initial fusion.

184. A July 21, 2008 report indicates that a patient developed massive neck swelling, very thick tracheal and bronchial secretions, and required a tracheostomy—a procedure in which an incision is made in the neck and a tube inserted to allow the patient to breathe—following a cervical fusion procedure with INFUSE™. These are only a few examples of the hundreds of similar reports of serious complications related to off-label uses of INFUSE™ found on the MAUDE Database.

185. Through MEDTRONIC's monitoring procedures—which include written procedures for complaints, corrective and preventative actions and adverse event reporting—all complaints and adverse events are documented, tracked, and trended (or should be) in a database. MEDTRONIC is required by federal regulation to "establish and maintain" such an adverse event database. *See* 21 C.F.R. § 803.1(a). In addition, a report from a June 2006 FDA inspection of a MEDTRONIC facility at 1800 Pyramid Place in Memphis, Tennessee, revealed that MEDTRONIC had initiated a Preventative Action, dated April 21, 2006, and was "studding [sic] the reason for an increase in the number of reported fluid collection, hematoma, and seroma complaints since 4/2005." According to the report, the "study indicated that sales for the INFUSE™ Bone Graph [sic] have increased and more graphs [sic] are being implanted," and that the "study is still open."

186. According to Confidential Witness #15 ("CW 15") in the *Minneapolis Firefighters* lawsuit filed against MEDTRONIC, more fully discussed *supra*, a Senior Vice President who worked at MEDTRONIC for numerous years until 2006 and a "Quality Group" at MEDTRONIC's Spine division were responsible for addressing adverse events. According to CW 15, former COO Michael DeMane, former President of MEDTRONIC Spinal and Biologics Mr. Wehrly, and former Worldwide Vice President and General Manager, Biologics, Jon Serbousek, were all aware of the adverse events related to INFUSE™. As a part of his employment with Defendants, CW 15 discussed the complaints related to INFUSE™ at meetings with these individuals and members of the Quality Group to decide whether or not certain adverse events should be reported to the FDA. Moreover, MEDTRONIC's Spinal division used the very same complaint/adverse event reporting system as MEDTRONIC corporate, which provided MEDTRONIC's executive officers access to a database containing details of every complaint/adverse event MEDTRONIC received relating to INFUSE™.

187. MEDTRONIC was further clearly aware of its settlement with the Department of Justice ("DOJ") and entry into a Corporate Integrity Agreement, discussed *supra*, in July of 2006. As a result, MEDTRONIC had actual knowledge of the heightened risks to spine patients associated with MEDTRONIC's illegal, improper, and unethical promotion of off-label use of INFUSE™ by MEDTRONIC's Spinal or Biologics Divisions.

5) **INFUSE™ is Profitable and thus MEDTRONIC had an Economic Motive to Promote INFUSE™ Off-label.**

188. INFUSE™ has become a best seller for MEDTRONIC. MEDTRONIC's INFUSE™ sales have exceeded $3.6 billion since the launch of the INFUSE™ Bone Graft in July 2002. As a J.P. Morgan research analyst covering MEDTRONIC noted in a report dated November 12, 2008:

> INFUSE™ is an $800M product for MEDTRONIC (6% of sales), having enjoyed robust growth since its initial approval in the U.S. in July 2002. In fact, it is the one piece of MEDTRONIC's Spine business that continues to post strong double-digit growth without any issues (LTM: +16.9%). That is, until now.

189. MEDTRONIC has depended heavily on INFUSE™ sales because so many of its other products, such as cardiac defibrillators, have slowed as the result of recalls of those defective defibrillators in the past several years.

190. Revenue generated by sales of INFUSE™ was approximately $800 million for the 2011 fiscal year, and the vast majority of these sales were attributable to off-label use of the product. Off-label uses of INFUSE™ account for 85% to 90% of all spine surgeries involving INFUSE™.

191. Plaintiffs are informed and believe and based thereon allege that, as a result of MEDTRONIC's illegal and improper off-label promotion, sales of INFUSE™ have soared and have totaled more than 4 billion of dollars from 2002 to 2011.

192. MEDTRONIC has consistently sought to expand the use of INFUSE™ by, among other things, illegally and improperly promoting dangerous and/or insufficiently studied off-label uses for INFUSE™ in various parts of the spine for various types of spine surgeries, as discussed throughout this Complaint.

6) MEDTRONIC Improperly Promoted Off-Label Uses of INFUSE™.

a) Generally

193. In spite of the very specific and limited FDA approval of INFUSE™ (for ALIF procedures only), the overwhelming majority of MEDTRONIC's INFUSE™ sales have been driven by non-FDA approved, or "off-label," uses, such as that used on the Plaintiffs in this civil action. Until recently, MEDTRONIC was very successful (and profitable) in driving off-label sales of INFUSE™ through undisclosed "consulting" and royalty agreements with physicians who, in exchange for handsome sums of money from MEDTRONIC or lavish trips paid for by MEDTRONIC, would push off-label usage in a number of ways, including by authoring scientific and medical literature promoting such uses, and by direct advocacy to other spine surgeons.

194. MEDTRONIC also directed its own sales representatives to promote off-label uses of the product, many of whom went so far as to recommend dosages of this potent molecule

in risky off-label procedures, and guide surgeons through off-label uses of the product during surgery. Indeed, MEDTRONIC's unlawful off-label promotion campaign was so extensive that it caught the attention of, among others, the FDA (on numerous occasions), the United States DOJ, Congress, the United States Army, several major universities, multiple medical journals, numerous major newspapers, independent physicians, and investors.

195. Moreover, MEDTRONIC's unlawful off-label campaign has resulted in, among other actions, two whistleblower lawsuits (resulting in a multi-million dollar settlement with the DOJ, which included a Corporate Integrity Agreement), a shareholder derivative lawsuit that was recently settled for $85 million, several adverse regulatory actions by the FDA, and a congressional investigation (led by the United States Senate Committee on Finance).

196. Indeed, even following MEDTRONIC's settlement with the DOJ in 2006 for unlawful kickbacks to physicians to use and promote its products, and corresponding entry into a Corporate Integrity Agreement ("CIA"), discussed *supra*, MEDTRONIC failed to disclose its continued reliance on kick-backs, royalties, and other undisclosed payments to physicians to drive INFUSE™ sales, primarily for off-label use.

197. Off-label use of INFUSE™ was and remains particularly concerning due to the known adverse (and in at least one case deadly) side effects known to MEDTRONIC at the time of the product's original FDA approval in 2002. Nonetheless, off-label use of INFUSE™ increased year-after-year from the time of its original limited use approval by the FDA in 2002, to the point where off-label use of INFUSE™ Bone Graft accounted for an astounding 85% to 90% of all INFUSE™ sales.

198. Although undisclosed by MEDTRONIC, the first-hand accounts of its former employees demonstrate that this extraordinarily high off-label use was driven by MEDTRONIC's sales force. Specifically, MEDTRONIC's marketing and sales employees directed spine surgeons to MEDTRONIC-compensated consultants or "Opinion Leaders" or "Thought Leaders" – other spine surgeons paid by enormous sums of money by MEDTRONIC – the sole purpose of which was to promote off-label uses of INFUSE™. Through these and other

illegal and improper practices, MEDTRONIC was able to increase INFUSE™ sales year after year while continuing to hide and downplay the product's dangerous side effects when used off-label in the spine.

199. MEDTRONIC actively promoted off-label use of INFUSE™ through its sales representatives and massive payments to its "Opinion Leader" spine surgeon consultants, which included sponsoring presentations at continuing medical education courses, and appearances at consulting engagements promoting off-label applications of INFUSE™. In turn, MEDTRONIC's sales force directed other physicians to these consultants and "Opinion Leaders" or to their written work (paid for by MEDTRONIC) to further drive off-label sales of INFUSE™. Indeed, MEDTRONIC engaged in such conduct even after its settlement of the whistleblower action with the DOJ in which it agreed to employ stricter compliance controls regarding the sale and marketing of its spine products.

200. The MEDTRONIC Defendants, while providing spine surgeons with MEDTRONIC-funded studies and published articles purporting to support the efficacy and safety of the off-label uses, simultaneously and systematically concealed or downplayed other non-MEDTRONIC-funded studies and articles demonstrating serious and frequent adverse events caused by the same off-label uses.

201. Several spine surgeons have already testified under oath at depositions that MEDTRONIC sales personnel overtly and directly promoted to them the off-label uses of INFUSE™ in the spine, and Plaintiffs are thus informed and believe that MEDTRONIC engaged in a scheme at all relevant times to expand its market share of this product by improperly encouraging such off-label uses.

202. In this particular case, MEDTRONIC actively promoted the off-label procedures to Plaintiffs' spine surgeon, and Plaintiffs' spine surgeons would not have performed the off-label INFUSE™ procedure in the absence of such promotion. MEDTRONIC's off-label promotion of INFUSE™ to Plaintiffs' surgeon was false and misleading, in that it overemphasized the purported benefits of the off-label use, and hid, minimized, or downplayed

the true risks and dangers of the off-label use, all of which were known to MEDTRONIC at all relevant times.

b) **Off-label Promotion of INFUSE™ Violates the Food, Drug, and Cosmetic Act.**

203. The FDCA specifically provides that the FDA has no authority to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship," and physicians are free to prescribe or use medical devices in any manner they deem medically appropriate. 21 U.S.C. § 396.

204. Importantly, however, medical device manufacturers such as MEDTRONIC cannot actively promote products for uses not approved by the FDA. Indeed, federal law provides for significant penalties for manufacturers that promote their products in ways inconsistent with a product's labeling. Severe penalties for off-label promotion, such as fines of up to twice the amount of the gross pecuniary gain from the offense, were designed to ensure that the FDA's careful, deliberate consideration of a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process. The MEDTRONIC Defendants are medical device companies, not physicians, and they are prohibited by federal law including the relevant FDA regulations, at all relevant times, from promoting to physicians or patients any off-label use of INFUSE™.

205. Under the FDCA and its accompanying regulations, a device manufacturer must include all intended uses in the label, otherwise the device is misbranded. 21 C.F.R. §801.4. Under the FDCA, device manufacturers can be held liable for off-label promotion when their products are deemed "misbranded" under the statute. 21 U.S.C. § 331(b).

206. A product is "misbranded" when the directions and indications for the unapproved uses that the manufacturer "intends" the product to be used for have not been included on the label. *See* 21 C.F.R. §801.4. Further, a device's intended uses are evidenced by the manufacturers' conduct, not by reference to what the FDA has approved. *Id.* A product's

intended uses can be derived from oral statements by persons speaking on behalf of a company about its product. In other words, a manufacturer can be liable under the FDCA if its conduct demonstrates intent to encourage product use inconsistent with or outside the scope of the product's approved label. *Id.*

207. The FDCA's accompanying regulations require that medical devices sold by manufacturers have adequate directions for use, 21 C.F.R. § 801.5, and failure to have adequate instructions for use is considered "misbranding," 21 U.S.C. § 352(f), which is prohibited. 21 U.S.C. § 331(b).

208. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling,[13] 21 U.S.C. § 321(n), and false or misleading labeling is considered "misbranding," 21 U.S.C. § 352(a), (q)(1), which is prohibited. 21 U.S.C. § 331(b).

209. Further, the FDCA requires medical device manufacturers to maintain and submit information as required by regulation, 21 U.S.C. § 360i, including submitting adverse event reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports. 21 C.F.R. § 820.198(a).

210. MEDTRONIC violated the FDCA statutes and accompany regulations by promoting INFUSE™ for off-label uses, and by failing to account for adverse events and update its labeling, directions for use, and advertising to account for the adverse events resulting from these off-label uses.

211. MEDTRONIC's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth below.

212. MEDTRONIC's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the off-label use of INFUSE™ generally, and directly caused or significantly contributed to the off-label use of INFUSE™ in

[13] 21 U.S.C. §321(m) defines the scope of medical device labeling.

this particular Plaintiff, and MEDTRONIC's misconduct in this regard thus caused or contributed to Plaintiff's injuries and damages.

c) **MEDTRONIC Settles Whistleblower Litigation with the DOJ and Agrees to Enter into a Corporate Integrity Agreement**

213. The MEDTRONIC Defendants were named as defendants in two *qui tam* actions, *United States ex rel. (UNDER SEAL) v. MEDTRONIC. Inc., et al.*, Civil Action No. 02-2709 (W. D. Tenn. 2002) (hereinafter "*[Under Seal]*"), and *United States ex rel. Poteet v. MEDTRONIC, Inc., et al.*, Civil Action No. 03-2979 (W. D. Tenn. 2003) (hereinafter "*Poteet I*"), (collectively the "qui tam lawsuits"), both of which alleged that MEDTRONIC violated the False Claims Act, 31 U.S.C. § 3729, *et seq.*, by paying illegal kickbacks to physicians in connection with promoting the off-label use of INFUSE™ in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

214. Based on its investigation, the DOJ contended that certain of the payments, services, and remuneration mentioned above were improper and resulted in the submission of false or fraudulent claims in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq.*, which prohibits individuals from offering, soliciting or making any payment or remuneration to induce business reimbursed under a federal or state health care program, and the False Claims Act, 31 U.S.C. § 3729, *et seq.*, which provides penalties for the submission of false claims to the federal government. Both *[Under Seal]* and *Poteet I* were brought by MEDTRONIC's former employees who made these allegations.

215. In these lawsuits, the DOJ contended that between January 1, 1998 and April 30, 2003, MEDTRONIC made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for physicians' attendance and expenses at medical education events, "think tanks," VIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians through MEDTRONIC's Healthcare Economic Services and eBusiness

Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities.

216. Specifically, *[Under Seal]* was brought by a former MEDTRONIC in-house counsel, who alleged that MEDTRONIC's "aggressive and illegal" sales and marketing efforts were intended by MEDTRONIC to improperly induce physicians to use MEDTRONIC's Spinal products, including INFUSE™. The conduct alleged included, *inter alia*: (1) lucrative consulting and royalty agreements with physicians that used MEDTRONIC Spinal products, "the true purpose [of which were] to funnel money to the physicians so that they will be induced to use [MEDTRONIC Spinal] products;" and (2) "[l]avish all-expense paid trips to fine resorts . . . disguised as Medical Education seminars, think tanks, or discussion groups . . . held in places such as Hawaii, Cancun, Alaska, Beaver Creek, Whistler, Malaysia, Amelia Island, Teton Valley, and New Orleans at Mardi Gras . . . [t]he purpose of these lavish trips was to induce the physicians to use [MEDTRONIC Spinal] products."

217. The complaint further alleged that: "Most of the illegal kickback practices described herein were begun by Sofamor Danek and continued by [MEDTRONIC] after the acquisition. Kickbacks were the culture and way of doing business at Sofamor Danek and the company was determined to continue that culture, and did continue that culture, when Sofamor Danek became part of the MEDTRONIC empire."

218. *Poteet I* brought by a former MEDTRONIC employee who was tasked by MEDTRONIC to arrange travel (including expense reimbursement) for numerous spinal surgeons to attend MEDTRONIC-sponsored events and other professional meetings. This former employee also alleged that MEDTRONIC paid surgeons substantial fees—sometimes up to hundreds of thousands of dollars per year—for consulting services that were grossly in excess of their fair market value, entered into royalty agreements that were designed to disguise illegal remuneration, and provided physicians opportunities for lavish travel and recreational activities, including "upgraded lodging for physicians, dinners, entertainment and activities such as golf, snorkeling, sailing, fishing, shopping trips, [and] horse-back riding" for using MEDTRONIC

products. These consulting agreements and other payments were illegitimate means of inducing physicians to use MEDTRONIC products and to recommend to other physicians that they do the same.

219. On July 18, 2006, MEDTRONIC agreed to pay $40 million to the United States of America to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12.

220. As part of the DOJ settlement, MEDTRONIC agreed to enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General/Health and Human Services that, as MEDTRONIC described in its July 18, 2006 press release, implemented substantial oversight structures and procedures meant to ensure "top-level attention to corporate compliance measures." Among other things, the CIA required MEDTRONIC to establish an electronic database to capture and manage all non-sales related transactions between MEDTRONIC's Spinal segment and its physicians or customers, with all such transactions subject to an established set of internal controls and review processes, including monitoring by MEDTRONIC senior management and MEDTRONIC's Chief Compliance Officer.

221. Moreover, the CIA required MEDTRONIC to implement internal policies and procedures to ensure stricter regulatory compliance, which obligated MEDTRONIC to institute a number of changes to improve oversight of its Spinal division.

222. Significantly, the CIA required MEDTRONIC to adopt procedures to ensure that any "arrangements"—a term intended to cover physician consulting agreements and broadly defined as engagements involving "directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; [] between [MEDTRONIC] and any actual or potential source of health care business [e.g., physicians]"—would not violate federal law. Such procedures were to include, among other things: (1) creating a database of all existing and new or renewed arrangements; (2) tracking remuneration from MEDTRONIC to all other parties to such arrangements; (3) tracking service and activity logs to ensure that parties to an arrangement are

performing their duties under the applicable arrangement; (4) implementing procedures that ensure all arrangements are reviewed for adherence to the Anti-Kickback Statute; and (5) regular (at least quarterly) review by the MEDTRONIC Compliance Officer of the arrangements database along with reporting (at least quarterly) to the MEDTRONIC Compliance Committee.

223. The CIA and the previous whistleblower and wrongful termination litigation placed MEDTRONIC and its agents on actual notice that its practice of marketing, and promoting INFUSE ™ for off-label uses was improper and required wholesale change to avoid further adverse regulatory action or other liability.

224. As a result of this settlement, MEDTRONIC agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which MEDTRONIC agreed to a settlement concerning the conduct at issue in the False Claims lawsuits.

225. Nonetheless, MEDTRONIC's unlawful practices continued, as did MEDTRONIC's and Dr. Michelson's aggressive efforts to drive INFUSE™ sales by promoting off-label applications, such as precisely those used on the Plaintiff. MEDTRONIC has continued to improperly and illegally promote the off-label use of INFUSE™ for non-FDA-approved uses of the product. Indeed, it was motivated to do so knowing that, absent off-label use, sales of INFUSE™ would dramatically decline. In order to prevent a decline in sales revenue, MEDTRONIC continued to covertly employ the same lucrative "consulting" arrangements and other unlawful conduct to promote off-label uses of INFUSE™.

226. As a result of MEDTRONIC's undisclosed misconduct, the percentage of off-label INFUSE™ usage increased over time, including after the DOJ settlement on July 14, 2006. By 2011, off-label use of INFUSE™ constituted more than 90% of the total use of INFUSE™ in spinal fusion procedures.

227. Indeed, MEDTRONIC's unlawful marketing and promotion was so effective that a MEDTRONIC analyst from Bernstein Research noted in a November 21, 2006 report that

analysts were "expecting *continued indication expansion (e.g., recent dental approval and likely approval for posterior lateral fusion) for INFUSE™ to be the main driver for the spinal business* in the mid-term." (Emphasis added.) What this analyst and the public at large did not know was that, despite the limited FDA-approved applications of INFUSE™, MEDTRONIC continued to drive sales solely through off-label indications; and was doing so in spite of the CIA, the material risk of further regulatory action or other liability, and in conscious disregard for the health and welfare of spine patients such as the Plaintiff.

d) Testimony of Former Medtronic Employees Regarding Off-label Promotion of INFUSE™ in a Shareholder Derivative Action Against Medtronic.

228. A federal securities lawsuit filed on behalf of the Minneapolis Firefighters' Relief Association against MEDTRONIC, *Minneapolis Firefighters' Relief Assoc. vs. MEDTRONIC, Inc.*, Civil No. 08-6324 (PAM/AJB) (D.Minn., 2009), also alleged evidence of MEDTRONIC's egregious campaign of off-label promotion of INFUSE™, even after the CIA. MEDTRONIC's actions, described by the "Confidential Witnesses" ("CW"), included:

a. MEDTRONIC-sponsored physician meetings, during which MEDTRONIC would employ paid consultants – typically surgeons hand selected by MEDTRONIC – to present off-label presentations to local physicians. CW1, Consolidated Class Action Complaint dated August 21, 2009, at ¶ 93.

b. MEDTRONIC's instructions to its sales representatives regarding various off-label uses of INFUSE™, including how much of the biologic to use with off-label cervical fusions, the purpose of which was to instruct physicians regarding off- label uses. CW1, *Id.* at ¶ 94.

c. MEDTRONIC's directions to its sales representatives that they be present during off-label INFUSE™ surgeries "to assist and direct and give advice when asked." CW1, *Id.* at ¶ 95; CW2, *Id.* at ¶ 97; CW5, *Id.* at ¶ 101; CW6, *Id.* at ¶ 102.

d. MEDTRONIC's creation of sales quotas that were described by the CWs as impossible to reach without pushing off-label use. CW1, *Id.* at ¶ 95; CW9, *Id.* at ¶ 105; CW11, *Id.* at ¶ 107; CW12, *Id.* at ¶ 108.

e. MEDTRONIC sales representatives' references to data from published literature (presumably funded by MEDTRONIC) when questioned by surgeons, the purpose of which was to provide surgeons with information regarding proffered techniques for off-label procedures and to educate them regarding off-label uses. CW2, *Id.* at ¶ 96.

f. MEDTRONIC's development of smaller-sized Bone Graft kits under the guise of selling them for FDA-approved uses, when, in actuality, MEDTRONIC had designed them to be used in off-label cervical fusion surgeries. CW2, *Id.* at ¶ 97; CW7, *Id.* at ¶ 103.

g. Moreover, by comparing the number of units of rhBMP-2 with the sales of the LT-Cage™ component – which were packaged and sold separately – CW2, 11, and 12 determined that the driving force behind MEDTRONICs $750 million in sales of INFUSE™ was solely attributable to off-label uses. Although the FDA required the rhBMP-2 and LT-Cage™ to be used together, sales of the rhBMP-2 component greatly outpaced those of the LT-Cage™. component. CW2, *Id.* at ¶ 98; CW11, *Id.* at ¶ 107; CW12, *Id.* at ¶ 108.

h. When questioned by a physician about how to use INFUSE™ off-label, MEDTRONIC sales representatives directed physicians to other surgeons who used the product off-label and also would demonstrate or explain how to do so. CW3, *Id.* at ¶ 99; CW5, *Id.* at ¶ 101; CW6, *Id.* at ¶ 102; CW10, *Id.* at ¶ 106; CW11, *Id.* at ¶ 107.

i. MEDTRONIC held quarterly meetings in at least one sales region, during which a national biologics specialist would attend to explain how to conduct off-label applications of INFUSE™. CW3, *Id.* at ¶ 99.

j. MEDTRONIC directed its sales representatives to instruct physicians to use half the dose of rhBMP-2 during cervical fusion, and MEDTRONIC, aware of adverse events, instructed the representatives to tell physicians to use steroids to combat potential inflammation. CW4, *Id.* at ¶ 100; CW5, *Id.* at ¶ 101.

k. MEDTRONIC directed physicians using the product in cervical spine fusion to throw away a large portion, sometimes up to half, of the rhBMP-2 dosage. CW6, *Id.* at ¶ 102.

l. MEDTRONIC gave to physicians a small book containing no reference to MEDTRONIC, which contained information regarding the volume or dosage of rhBMP-2 that should be used for off-label applications of INFUSE™. CW7, *Id.* at ¶ 103; CW8, *Id.* at ¶ 104; CW9, *Id.* at ¶ 105.

m. MEDTRONIC instructed CW8 and others during sales presentations regarding how to "get around" restrictions on off-label promotion. CW8, *Id.* at ¶ 104.

n. CW13 was brought into MEDTRONIC to develop a marketing plan; which included: a) Development of a "referral marketing" campaign designed to promote the product for off-label uses via a physician referral network; b) identifying which surgeons would be targeted as part of MEDTRONIC's off-label campaign and what claims MEDTRONIC would make about the product; c) development of a "cookie- cutter" CD series that outlined MEDTRONIC's off-label campaign and included information on off-label procedures that was distributed to MEDTRONIC sales representatives. According to CW13, the referral marketing program involved having surgeons meet with other surgeons as a means of prompting discussion of off-label uses of INFUSE™ Bone Graft among practitioners. CW13 also stated that MEDTRONIC used a physician training program involving cadaver labs as a means to instruct surgeons regarding off-label applications. CW13, *Id.* at ¶ 109.

o. CW13 was rebuffed for raising concerns about off-label promotion, and was told "we're paying you a lot of money to launch this. Shut your mouth and take the money. Let us worry about what is off-label or isn't." CW13, *Id.* at ¶ 110.

p. A sales representative was present in the operating room during an off-label cervical procedure which led to the patient's death. The patient's family subsequently initiated civil litigation against MEDTRONIC and the sales representative who was allegedly encouraging the off-label procedure at MEDTRONIC's behest. *Id.* at ¶ 111.

q. Although MEDTRONIC is under an obligation to report all serious adverse events associated with INFUSE™, MEDTRONIC failed to report the death of this patient until three months after it occurred. FDA guidelines recommend that a manufacturer make a minimum of three attempts to retrieve additional information regarding any adverse event. While the company filed an adverse event report with the FDA in which it noted the complications immediately following the procedure, MEDTRONIC did not inform the agency of her death until after a lawsuit was filed by the patient's family and reported in *The Wall Street Journal*. *Id.* at ¶ 112.

r. In a separate civil suit against MEDTRONIC, a physician admitted to attending numerous national spine meetings during which off-label uses of rhBMP-2 in the cervical spine were promoted. A MEDTRONIC sales representative was in the operating room a lot when he was performing off-label uses. He admitted to doing over 100 cervical procedures, insinuating that the MEDTRONIC sales representative was in the room for a fair number of these procedures. *Id.* at ¶ 113.

229. The plaintiffs in the *Minneapolis Firefighters* lawsuit also discovered the growing percentage of off-label INFUSE™ usage from 2003-2007 by analyzing surgical procedural codes

used by hospitals.[14] The results of this analysis demonstrate that off-label usage of INFUSE™ was high, even from the inception of FDA approval, and increased by an astonishing 10% over the next 4 years; to wit:

230.

Year	Estimated On-Label Procedures	Estimated Off-Label Procedures
2003	25.7%	74.3%
2004	20.6%	79.4%
2005	15.8%	84.2%
2006	15.3%	84.7%
2007	14.8%	85.2%

230. Moreover, the data further demonstrate that off-label use of INFUSE™ in the cervical spine grew to as much as 18% of overall INFUSE™ use as of 2007, despite the known increased medical risks associated with that application.

231. Indeed, to set sales projections for INFUSE™, CW 2 stated that MEDTRONIC's marketing department accounted for the scope and number of procedures performed, including the numbers of off-label procedures, such as PLIFs and TLIFs, to predict sales projections. This analysis was based, in part, on data purchased from market research companies demonstrating the number of procedures involving different areas of the spine, e.g., certain lumbar (on- or off-label) versus cervical (off-label). Once MEDTRONIC determined its sales projections, these figures were incorporated into a budget presented to MEDTRONIC's senior management. Importantly, the final sales quotas for INFUSE™ were dictated by MEDTRONIC senior management, and were far in excess of what MEDTRONIC's Spinal Division had projected, or could be achievable absent promotion of the product for off-label uses. According to CW 2, "when the numbers came back down, they never reflected the projections. They were much larger."

[14] The methodology employed was consistent with a July 1, 2009 report in the JAMA that conducted a retrospective cohort study of 328,468 patients undergoing spinal fusion procedures from 2002-2006, using the same codes from the NIS database.

232. Numerous confidential witnesses, including CWs 1, 9, 12 and CW 14 (a senior manager for MEDTRONIC's Spinal and Biologics division from 2005 to 2008), confirm the intense pressure MEDTRONIC's management placed on its sales representatives to meet the sales quotas the company set. Like CW 2, CW 14 explained that sales goals were set by a handful of MEDTRONIC executives, and that they were "very, very, very aggressive." Likewise, CW 12 stated that there was a lot of pressure on MEDTRONIC's Spinal and Biologics division to reach unreasonable sales targets.

233. As demonstrated, by years 2006-07, off-label uses accounted for an astounding 85% of INFUSE™ sales; a fact known or recklessly disregarded by all employees, who reviewed marketing data and analyses to set sales quotas for INFUSE™. Indeed, sales quotas for INFUSE™ required sales to grow 20% year-over-year, and MEDTRONIC knew that such increases could not be achieved without substantial off-label sales, and thus that such aggressive targets would encourage off-label promotion by its employees and representatives.

e) **MEDTRONIC's Payments to Opinion Leaders.**

i) **Generally.**

234. In addition to encouraging its sales representatives to promote off-label use of INFUSE™, MEDTRONIC also promoted the off-label use of the product through its outside physician "Opinion Leaders" to whom MEDTRONIC paid undisclosed sums in return for publishing medical journal articles and delivering presentations explaining, endorsing, and promoting off-label applications of the product. Indeed, even after settlement with the DOJ and entry into the CIA as a result of this very activity, MEDTRONIC continued its practice of providing lucrative consulting fees (amounting to millions of dollars per year) to surgeons who actively promoted off-label use of INFUSE™, often with direct involvement by MEDTRONIC's senior management.

235. MEDTRONIC has sought to expand the off-label uses (and has succeeded in doing so) by paying large amounts of money to key "Opinion Leader" spine surgeons around the

country, many of whom then published studies and articles advocating the off-label use of INFUSE™ and minimizing the risks or dangers to patients from these uses.

236. Medical device companies look for surgeons who are known as "Opinion Leaders" and who will not only use a high volume of their products, but who can and will persuade other surgeons to use a particular device. Opinion leaders are physicians whose opinions on medical procedures and medical devices are held in high regard by other surgeons. If these influential physicians are willing to promote the use of a certain device, then other surgeons are likely to follow suit and use that device, sometimes including off-label uses which are illegal for the company itself to promote.

237. Many medical device companies, including MEDTRONIC, cultivate relationships with these "Opinion Leaders," paying them handsome (and in the case of INFUSE™, sometimes seven-figure) consulting fees, travel expenses for seminars, sham or exaggerated royalty payments, and numerous other perks, to encourage these physicians to promote the use of a particular medical device.

238. Prior to the date of Plaintiff's spine surgery which involved off-label INFUSE™, MEDTRONIC provided millions of dollars in undisclosed payments to certain spine surgeon "Opinion Leaders" who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements to promote off-label applications of INFUSE™ in the spine. In turn, MEDTRONIC's sales force would direct other physicians to these "Opinion Leaders" or to their written work to further drive off-label sales of the INFUSE™. In this way, MEDTRONIC consciously and deliberately orchestrated a campaign to end-run the FDA's 2002 approval of and labeling for the INFUSE™ device.

239. MEDTRONIC, for example, paid more than $45 million to the 12 spine surgeons who authored the first 13 studies sponsored by MEDTRONIC on INFUSE™. Additionally, "Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty, and

other miscellaneous arrangements." *Staff Report on Medtronic's Influence on INFUSE™ Clinical Studies*, U.S. Senate Committee on Finance, October 25, 2012.

ii) **Walter Reed "Opinion Leaders:" Timothy Kuklo, M.D., Rick Sasso, M.D., and David Polly, M.D.**

240. Just one of MEDTRONIC's highly compensated "consultants"—Dr. Timothy Kuklo, a former Army physician who retired from the military as chief of orthopaedic surgery at Walter Reed Army Medical Center ("Walter Reed"), the nation's premier military research hospital in December 2006—received hundreds of thousands of dollars per year in fees in the years following the DOJ settlement. Specifically, *The Wall Street Journal* and *New York Times* reported in 2009 that Dr. Kuklo received $356,242 in 2007, $249,772 in 2008 and $132,453 in the first few months of 2009 from MEDTRONIC for consulting, speaking, travel, and training services. MEDTRONIC paid Dr. Kuklo $42,627 in 2006 while he was still on active duty at Walter Reed, as well as amounts totaling $42,295 from 2001 through 2005, primarily for travel to medical conferences and speeches at MEDTRONIC events, including direct payments to hotels and airlines. MEDTRONIC confirmed that Dr. Kuklo was a paid consultant for MEDTRONIC and that the company has paid him more than $800,000 over an eight year period.

241. While it is not inherently illegal or unethical for physicians to perform paid consulting work for medical device companies, the history of the growing INFUSE™ scandal demonstrates an egregious pattern of both MEDTRONIC and its "Opinion Leaders" overstepping ethical lines while recklessly promoting dangerous off-label uses of this product. Dr. Kuklo, for example, worked closely with MEDTRONIC as an active promoter of off-label uses of INFUSE™; that is, until a U.S. Army investigation into a falsified study touting the benefits of INFUSE™ uncovered shocking misconduct by this former Army surgeon. For example, Dr. Kuklo appeared as a "distinguished guest surgeon" at a MEDTRONIC Spine Division Business Overview Conference Call on September 28, 2006, alongside another MEDTRONIC consultant, Dr. Rick Sasso—who received $150,000 in consulting fees in 2006—as well as Ellis and Peter Wehrly ("Wehrly"), MEDTRONIC Spinal Division Senior Vice

President. During the call, a Merrill Lynch analyst asked about "issues that have come up in the past in terms of potential side effects with using INFUSE™ in the cervical region," and whether such off-label use was a concern for surgeons. Dr. Sasso responded by referring to a "Level 1, controlled randomized study which was published in 2002" which, according to Dr. Sasso, demonstrated that "when you used the appropriate dosage of INFUSE™, you did not get problems with esophageal obstruction and problems swallowing." For his part, Dr. Kuklo responded that the question "was well answered as far as appropriate dosage. I think it's really the bottom line."

242. Although Dr. Kuklo's and Dr. Sasso's rendition of the medical literature may not have been entirely accurate—in fact they baldly misrepresented the seriousness of the adverse events that MEDTRONIC knew were occurring in the cervical spine—their misrepresentations only hinted at the influence of MEDTRONIC's payments on its consultants' medical judgment. Indeed, an Army investigation later revealed that Dr. Kuklo deliberately falsified data by exaggerating the benefits of off-label use of INFUSE™ in a study published in the August 2008 issue of *The Journal of Bone and Joint Surgery*.

243. Dr. Kuklo's "study," which purported to compare fusion results of sixty-seven (67) patients who received an autogenous bone graft versus sixty-two (62) that were treated with INFUSE™ to treat certain tibial (shin bone) fractures in injured soldiers (including certain off-label uses), reported that employing INFUSE™ resulted in "strikingly" better outcomes than a traditional (autogenous) bone graft. Specifically, Dr. Kuklo reported that those receiving autogenous bone grafts had successful fusions in 76% of procedures, while the union rate for the INFUSE™ group was significantly better at 92%; a claimed "striking finding."

244. According to Dr. Kuklo, not only were the reported union rates claimed better with INFUSE™ than with an autograft, but, according to this (falsified) study, patients who received INFUSE™ also reportedly experienced favorable outcomes in other clinical measures. Specifically, the study concluded that "the primary outcome measures of union, rate of infection,

and reoperation were all improved with rhBMP-2," and that those treated with INFUSE™ had a "strikingly lower infection rate (3.2%), which we believe is directly attributable to rhBMP-2."

245. MEDTRONIC continued paying Dr. Kuklo as a consultant even after his article was discovered to be largely fabricated and thus retracted by *The Journal of Bone and Joint Surgery*. Indeed, MEDTRONIC only placed Dr. Kuklo on "inactive status" after reports that he had falsified the study's data were published in *The New York Times*.

246. On May 13, 2009, *The New York Times* reported that the U.S. Army's investigation into a study authored by Dr. Kuklo concluded that he falsified an entire study touting the benefits of INFUSE™ to treat wounded soldiers injured in Iraq – conduct that Col. J. Edwin Atwood, an Army physician who led the Army's inquiry, described as "the ultimate tragedy and catastrophe in academic medicine."

247. Per *The New York Times* and *The Wall Street Journal*, the true facts regarding Dr. Kuklo's study were only uncovered when one of the study's supposed "co-authors," Lt. Col. Romney C. Andersen, was congratulated on its publication by a colleague. After this discovery, Lt. Col. Andersen alerted Army investigators who found that:

a. Dr. Kuklo listed four other Army surgeons as "co-authors" without their knowledge, and these four physicians did not participate in or review the article's preparation or submission for publication;

b. The signatures of the four physicians listed as co-authors on the copyright release forms submitted to *The Journal of Bone and Joint Surgery* were forged by Dr. Kuklo;

c. The number of cases cited by Dr. Kuklo in the article differed from the number of cases contained in the U.S. Army's wartime casualty database, with no explanation for the discrepancies in the article;

d. Contrary to Army policy, Dr. Kuklo did not obtain publication review or clearance from Walter Reed prior to submitting the article for publication; and

e. The published results of the article suggested a much higher efficacy rate for INFUSE™ than is supported by the experience of the purported co- authors.

248. According to one of the Army's investigators, Col. Norvell V. Coots, the study cited higher numbers of patients and injuries than the hospital could account for having as patients. According to Col. Coots, "It's like a ghost population that were reported in the article as having been treated that we have no record of ever having existed ... this really was all falsified information."

249. After receiving correspondence from Walter Reed dated November 6, 2008 stating that Dr. Kuklo did not follow Army regulations in submitting the article, that the signatures of the purported co-authors had been forged, and that the article's purported co-authors had questioned the study's findings, *The Journal of Bone and Joint Surgery* formally retracted the article and banned Dr. Kuklo from submitting further papers to *The Journal of Bone and Joint Surgery*. As noted in a May 19, 2009 follow-up article in *The New York Times*, when questioned about its ties to Dr. Kuklo, MEDTRONIC repeatedly declined to disclose when it began its financial relationship with him or the extent of funding it provided.

250. As discussed in more detail *supra*, U.S. Senator Charles Grassley discovered that Dr. Kuklo's name did not appear on a list of paid consultants for INFUSE™ provided by MEDTRONIC that the Senator had requested in a September 30, 2008 letter to MEDTRONIC. Senator Grassley disclosed the list MEDTRONIC provided—which included twenty-two (22) physicians who were paid a total of $943,000 from 2005 to 2008—in a May 18, 2009 letter to MEDTRONIC that was published in the Congressional Record the following day. According to the May 18, 2009 letter, Senator Grassley was "concerned" that MEDTRONIC did not provide Dr. Kuklo's name in response to his inquiry that specifically requested information regarding consultants who work on INFUSE™, as it was "clear that Dr. Kuklo had some sort of consulting agreement" and was named in *The New York Times* as a consultant on INFUSE™. Indeed, by this time, Dr. Kuklo had given countless presentations on behalf of MEDTRONIC about off-label use of the product.

251. The list provided to Senator Grassley also omitted names of other MEDTRONIC consultants who had promoted off-label uses of INFUSE™, such as David Polly, M.D., another former Walter Reed surgeon. Frustrated with MEDTRONIC's omissions, Senator Grassley stated that "[i]n the future, I hope that instead of not providing me with the name of the physician involved in INFUSE™, or any other matter that I am looking into, that MEDTRONIC contact me to avoid the situation in which we find ourselves." A May 19, 2009 *New York Times* article reported that MEDTRONIC also faced a DOJ inquiry regarding its illegal promotion of INFUSE™.

252. As a result, on June 18, 2009, MEDTRONIC disclosed to *The Wall Street Journal* that Dr. Kuklo had received almost $850,000 in payments from MEDTRONIC over the past 10 years, the majority of which—nearly $800,000— were made in the preceding three years when Dr. Kuklo was submitting his bogus fabricated study on INFUSE™ to medical journals for publication. Specifically, MEDTRONIC paid Dr. Kuklo $356,242 in 2007, the year Dr. Kuklo sought publication of the study in two medical journals, and $249,772 in 2008, the year the study was published in the *Journal of Bone and Joint Surgery*. MEDTRONIC made both of these payments after MEDTRONIC announced the settlement with the DOJ in July 2006.

253. In July 2009, Senator Grassley also publicly disclosed information demonstrating that Dr. Kuklo hid his financial relationship from Washington University and failed to disclose his financial ties in conflict-of-interest disclosure forms while he was conducting research related to INFUSE™. In fact, MEDTRONIC financed two separate, unpublished studies that also examined the use of INFUSE™ on Walter Reed patients with combat-related leg injuries while Dr. Kuklo was supposedly conducting research for the falsified study. At the time Washington University approved the study protocols, Dr. Kuklo indicated on disclosure forms that he did not receive any payments from MEDTRONIC when, in fact, Dr. Kuklo signed a contract with MEDTRONIC shortly after joining the Washington University faculty and had received payments from MEDTRONIC for almost a year into his research.

254. In mid-2007, after Dr. Kuklo disclosed to Washington University that he had received funding from MEDTRONIC, the University's internal disclosure review board re-reviewed Dr. Kuklo's involvement in the MEDTRONIC-sponsored studies and informed him he would have to reduce his personal financial interest with MEDTRONIC to less than $10,000 per year or discontinue his involvement with the research. Dr. Kuklo opted to stop the two studies, which were closed in February 2008.

255. Another highly compensated MEDTRONIC consultant involved in the promotion of off-label INFUSE™ use, Dr. Polly, a professor and Chief of the Spine Service at the University of Minnesota, Department of Orthopaedic Surgery, received consulting fees from MEDTRONIC totaling $1.14 million from 2003 to 2007. As with Dr. Kuklo, MEDTRONIC's financial relationship with Dr. Polly began while the surgeon was on active military duty at Walter Reed. Although Dr. Polly has claimed that his consulting relationship with MEDTRONIC did not begin until 2004, documents obtained through requests under the Freedom of Information Act ("FOIA") reveal that MEDTRONIC paid almost $30,000 in travel expenses for Dr. Polly to speak at various medical conferences in the Bahamas, San Diego, and a $10,000 trip to Switzerland, while he was stationed at Walter Reed in 2003. Dr. Polly attended these conferences to report on his research that purportedly demonstrated that INFUSE™ was more cost effective than traditional spinal fusion procedures.

256. After his discharge from the military, Dr. Polly authored an article with Dr. Kuklo reporting positive results in treating wounded soldiers with rhBMP-2 at Walter Reed. According to their article, published in the November 2004 issue of "Minnesota Medicine," rhBMP-2 was used in more than 100 military patients with traumatic bone fractures who had served in Iraq and Afghanistan. Although the use of INFUSE™ in tibial fractures was not approved until April 30, 2004, Dr. Polly reported that the "decision to use rhBMP-2 was made early in the Afghanistan conflict and was based on evidence from clinical trials in Europe on open tibial fractures that suggested use of rhBMP-2 not only improved bone healing but led to a decreased number of

secondary interventions and lower rates of infection." According to Dr. Polly, "the military's experience with rhBMP-2 has been favorable."

257. Moreover, additional evidence demonstrates that, even before his and Dr. Polly's November 2004 article was published, MEDTRONIC reimbursed Dr. Kuklo for a meeting with MEDTRONIC representatives in Memphis, Tennessee on April 20, 2004 regarding "Review of BMP Trauma and Spine Surgery."

258. Dr. Polly later sought a government grant for a similar study in May 2006, when he testified before the Defense Subcommittee of the U.S. Senate Appropriations Committee regarding research that would examine the use of INFUSE™ and antibiotics to treat traumatic and infected bone fractures. Dr. Polly stated that he was "speaking on behalf of the American Academy of Orthopedic Surgeons." However, according to information recently released by Senator Grassley, who, in conjunction with Senator Baucus, has been conducting an inquiry into MEDTRONIC's consulting payments, Dr. Polly actually billed MEDTRONIC $7,000 in connection with his Senate testimony, and was therefore speaking on behalf of MEDTRONIC, not the American Academy of Orthopedic Surgeons, as he had claimed. Furthermore, Dr. Polly billed MEDTRONIC a total of $50,000 over several months for his lobbying efforts in securing the $466,644 Department of Defense grant for this INFUSE™ research study.

259. The information released by Senator Grassley, discussed more fully *supra*, which includes billing reports submitted to MEDTRONIC by Dr. Polly and approved by MEDTRONIC, indicates that throughout this period, Dr. Polly had frequent meetings, telephone calls, and email correspondence with numerous MEDTRONIC senior executives, including former COO Michael DeMane ("DeMane"), and former President of MEDTRONIC Spinal and Biologics Wehrly, while speaking frequently regarding INFUSE™ at medical conferences and other events. For example, the records show meetings and other contacts between Dr. Polly and Hawkins on the following dates: February 13, 2007; June 15, 2007; July 27, 2007; August 8, 2007; August 24, 2007; September 26, 2007; and September 27, 2007. Indeed, they further show

that Dr. Polly billed MEDTRONIC for a meeting with Hawkins on July 13, 2005 to discuss a "spine surgery advocacy effort."

iii) Opinion Leader Dr. Thomas A. Zdeblick.

260. Thomas A. Zdeblick, M.D., the Chairman of the Department of Orthopedics and Rehabilitation at the University of Wisconsin, received over $19 million from MEDTRONIC from 2003 to 2007 for consulting services and royalty payments. Although Dr. Zdeblick only disclosed annual payments exceeding $20,000 in University conflict of interest forms, he actually received between $2.6 and $4.6 million per year. In 2007 alone, Dr. Zdeblick received $2,641,000 in consulting fees from MEDTRONIC. From 1998 through 2004, Dr. Zdeblick was paid an annual salary of $400,000 by MEDTRONIC under a contract that only required him to work eight days per year at a MEDTRONIC site in Memphis, Tennessee, and to participate in "workshops" for surgeons.

261. Dr. Zdeblick also has been a significant contributor to MEDTRONIC's promotion of INFUSE™, authoring seven peer-reviewed articles on rhBMP-2 and appearing as a presenter at medical conferences and symposia in which the topics included discussion of off-label uses of the product. On a MEDTRONIC-owned website, "www.Back.com," Dr. Zdeblick describes the advantages of INFUSE™ and appears in an online video discussing the benefits of the product.

262. As discussed more fully *supra*, on January 16, 2009, *The Wall Street Journal* reported on a letter sent by Senator Charles Grassley to Kevin P. Reilly, President at the University of Wisconsin, regarding Defendants' consulting and royalty payments to Dr. Zdeblick, who co-authored preliminary studies that led to the FDA's approval of INFUSE™. Although the University is required to monitor its researchers' financial conflicts-of-interest, the amounts MEDTRONIC paid Dr. Zdeblick far exceeded those he reported to the University. Specifically, Dr. Zdeblick was required to disclose annual amounts in excess of $20,000 per year, and in one year reported payments in excess of $40,000. In reality, Dr. Zdeblick received between $2.6 million and $4.6 million per year from MEDTRONIC, totaling an astonishing $19 million in payments, from 2003 through 2007.

263. As revealed in a June 20, 2009 article in the *Milwaukee Journal Sentinel*, Dr. Paul A. Anderson, an orthopedic surgeon and colleague of Dr. Zdeblick at the University of Wisconsin School of Medicine and Public Health, was paid $150,000 by MEDTRONIC for just eight days of work. Dr. Anderson, along with MEDTRONIC consultants Drs. Boden, Keith H. Bridwell, and Jeffrey C. Wang, authored a July 2007 article in *Journal of Bone and Joint Surgery* article, titled "What's New in Spine Surgery." The article discussed, among other things, a study that examined the use of INFUSE™ in an off- label Posterolateral Fusion procedure. According to the authors, the study reported that INFUSE™ improved fusion rates when used in combination with iliac crest bone graft in a procedure in which the BMP was wrapped around local bone as a bulking agent. According to the authors, the study's findings suggested that "the current [INFUSE™] kit, while likely not sufficient as a stand-alone graft substitute for the posterolateral spine, can provide a significant enhancer effect, improving the success of an autogenous bone graft."

264. On June 20, 2009, the *Milwaukee Journal Sentinel* reported that, during calendar year 2008, MEDTRONIC paid Dr. Zdeblick $2 million in royalty payments for eight days of consulting work, and that Dr. Paul Anderson received $150,000 in MEDTRONIC consulting fees for working just eight days.

iv) Norton Hospital Leatherman Spine Center Opinion Leaders.

265. Another set of highly compensated surgeons, those affiliated with the Norton Hospital Leatherman Spine Center in Louisville, Kentucky, collectively received more than one million dollars in consulting fees in 2006 alone, including Drs. John R. Johnson ($162,750), Steven D. Glassman ($200,300), Rolando M. Puno ($106,000), John R. Dimar, II ($192,300), David Rouben ($109,300), Mitch Campbell ($212,000) and Mladen Djurasovic ($55,900).

266. According to CW 1, several surgeons from the Leatherman Spine Center were requested by MEDTRONIC to speak at MEDTRONIC-sponsored physician talks attended by between ten and twenty-five surgeons, including several "pretty high profile" physicians. At these physician talks, a MEDTRONIC consultant, such as one of the surgeons at the Leatherman

Spine Center, provided presentations covering the purported benefits of off-label usage of INFUSE™. According to CW 1, "What [MEDTRONIC] would do is bring in one of their 'paid consultants' and set up a dinner in the area and invited a number of physicians to attend." The guest surgeon—the "paid consultant"— would then "basically give a presentation on off-label usage." Importantly, these physician talks were also attended by all MEDTRONIC sales representatives who worked in the area.

267. These same MEDTRONIC-funded surgeons associated with the Leatherman Spine Center have also written extensively on off-label uses of INFUSE™. These surgeons have collectively authored at least 15 articles addressing the use of BMP, including many of the early medical articles on the use of INFUSE™ in off-label posterolateral lumbar and anterior cervical fusion procedures. Specifically, Dr. Campbell has contributed to at least eight articles examining the use of BMP; Dr. Dimar has authored nine; Dr. Djurasovic, four; Dr. Johnson, five; Dr. Puno, five; and Dr. Glassman has written at least fifteen articles addressing the use of BMP, the vast majority of which involve applications of the product in off-label procedures.

v) **Other Various Opinion Leaders.**

268. Several physicians who authored a May 2003 article describing positive results of INFUSE™ used in the cervical spine were paid tens of thousands of dollars in consulting fees by MEDTRONIC. The article, "New Technologies in Anterior Cervical Spine Fixation," published on Spine Universe, a website intended for the general public that provides information regarding spinal disorders and treatment, described the physicians' use of INFUSE™ "in the cervical spine with very good results." According to the authors, "[p]reliminary results are promising and INFUSE™ may be especially appropriate in people undergoing multiple level fusions" (emphasis added)—i.e., for indications outside FDA limited approval to single-level fusion procedures.

269. One of the authors of this article, Dr. Regis Haid, Jr., received consulting fees of $50,000 from MEDTRONIC in 2006 and similar amounts in the previous two years. Another author, Dr. Gerald Rodts, received payments of $80,000 from MEDTRONIC in 2006 and similar

amounts in the previous two years. The Spine Universe article does not mention that its authors received compensation from MEDTRONIC, nor do the website profiles of Dr. Haid and Dr. Rodts, both of whom serve on the publication's editorial board, disclose their financial ties to MEDTRONIC.

270. Dr. Haid was also the lead author of an article describing the results of the study of INFUSE™ in off-label PLIF procedures that was halted in December 1999 after several patients experienced adverse incidents of uncontrolled bony overgrowth. In addition, two of the article's other authors—Dr. J. Kenneth Burkus and Dr. Charles L. Branch—received consulting fees from MEDTRONIC. Specifically, MEDTRONIC paid Dr. Branch $154,900 in 2006 and similar amounts in the preceding two years, while Dr. Kenneth Burkus—who has written over a dozen articles addressing the use of rhBMP-2, including studies examining the use of INFUSE™ in off- label PLIF and anterior cervical procedures—received $416,775 in 2006 and similar amounts in the two preceding years.

271. Although the negative outcomes in the PLIF study prompted the FDA Advisory Panel to recommend a more restrictive labeling and indication in approving INFUSE™, the MEDTRONIC-funded authors reviewing the study's results surprisingly did not find the incidents of bony overgrowth to be a clinically significant concern. Shockingly, the physicians noted, "[a]lthough not desirable, bone formation in the spinal canal does not appear to have a discernible effect on patient outcomes," and "the de novo rhBMP-formed bone occurred predictably, not compressing the neural structures."

272. In a commentary on the study, Dr. Neil Kahanovitz, an independent surgeon, questioned the authors' interpretations, suggesting that they may have been "overwhelmed by their enthusiasm of using" rhBMP-2 in a PLIF procedure. Dr. Kahanovitz noted that, while there are "lengthy discussions of various trends throughout this study, which imply the superiority of rhBMP over autograft . . . one fact remains: in every clinical measure examined in this study, there were no statistically superior outcomes in the rhBMP group except one, and the clinical significance of this one statistically significant finding is unclear."

273. Importantly, Dr. Kahanovitz also disagreed with the authors' conclusion that the presence of bone growth in the spinal canal and foramina (the two apertures between vertebrae) in those patients who received rhBMP-2 had no clinical implications. Rather, Dr. Kahanovitz predicted that "most surgeons would be less than enthusiastic to see this statistically significant variable present in the majority of their patients."

274. CW 1 stated that Drs. Lawrence "Larry" G. Lenke and Keith H. Bridwell, two surgeons from Washington University in St. Louis – where Dr. Kuklo worked as an associate professor until recently – similarly acted as "Opinion Leaders" or "guest surgeons" during "corporate visits" in which MEDTRONIC would invite targeted surgeons to attend training sessions in Memphis, Tennessee. While in Memphis, the visiting surgeons met with MEDTRONIC corporate officers, product managers, and guest surgeons, such as Drs. Lenke and Bridwell. The visiting surgeons also received "hands-on training" on INFUSE™, including instruction in cadaver labs. According to CW1, who personally attended two such meetings, "[t]here was training on off- label procedures, for sure." The visiting surgeons "would bring up the use of INFUSE™ and ask how to use it, and [the guest surgeons] would show them how to do it." CW1 stated that MEDTRONIC chose which surgeons to invite to these corporate visits based, in part, upon the volume of INFUSE™ procedures they performed.

275. Another prominent MEDTRONIC consultant, Jeffrey Wang, M.D., the Chief of Spine Surgery for the Department of Orthopaedic Surgery and Executive Co-Director of the University of California, Los Angeles's ("UCLA") Comprehensive Spine Center, also spoke about off-label uses of INFUSE™. Unsurprisingly, Senator Grassley recently discovered that Dr. Wang received $275,000 in royalty and consulting payments from MEDTRONIC from 2003 until 2008.

276. Furthermore, Dr. Wang failed to disclose his substantial financial relationship with MEDTRONIC while researching MEDTRONIC products, which violated UCLA's policy requiring him to do so. For example, on a disclosure form to UCLA dated January 10, 2007, Dr. Wang checked "no" when asked if he received income of $500 or more from MEDTRONIC,

notwithstanding the fact that MEDTRONIC was, at that very moment, funding one of Dr. Wang's studies. In fact, Dr. Wang received $14,600 on January 4, 2007 for "lecture and teachings at spine meetings and universities in Korea for one week." As a result of his repeated failures to disclose payments received from MEDTRONIC, Dr. Wang lost his position as Executive Co-Director of UCLA's Comprehensive Spine Center.

277. As discussed more fully *supra*, Senator Grassley also discovered that, in addition to the compensation to MEDTRONIC consultants, MEDTRONIC collectively paid twenty-two other surgeons $943,000 from 2003 to 2008 to work on matters specific to INFUSE™.

278. In June 2011, one of the leading journals on spine surgery, *The Spine Journal*, described more fully *supra*, devoted an entire issue to publishing various articles regarding the risks associated with INFUSE™, including articles on MEDTRONIC's failure to accurately report the side effects from its clinical trials; MEDTRONIC's failure to report that many of the authors who studied and promoted INFUSE™ had significant financial ties to MEDTRONIC, with a median range of $12 to $16 million per study; that INFUSE™ can cause severe injuries to the spinal nerves and spinal cord; that off-label use of INFUSE™ can lead to other severe side effects; and that MEDTRONIC and its paid consultants/study authors downplayed the risks associated with INFUSE™, over-emphasized its benefits and over-emphasized the risks associated with traditional non-INFUSE™ spine fusion procedures.

vi) MEDTRONIC MANAGERS AND DR. MICHELSON

279. Defendant Medtronic Managers, in collaboration with other Defendants, and in furtherance of a business plan of Medtronic, intentionally and/or recklessly engage in vigorous and unlawful overpromotion of the off-label use of Infuse in California, and other states, through the use of consultants, sales representatives, key opinion leaders and other agents of Defendant Medtronic, for the purpose of misleading physicians, including, but not limited to the surgeons providing care to Plaintiff.

280. Critical here is that Defendant Medtronic Managers did, upon information and belief, pay certain orthopedic surgeons in California, including, but not limited to Drs. Jeffrey E.

Deckey, David Lee Skaggs, Todd Lanman, Theodore G. Obenchain, and certain physicians at the San Francisco Spine Institute, sums of money, in excess of $250,000.00, for services these healthcare providers did not render, in order to obtain testimonials and support for the off-label use of Infuse.

281. Each Defendant Medtronic Managers' activities did, in part, cause the introduction into the stream of commerce, the INFUSE product received by Plaintiffs.

282. Plaintiffs are informed and believe, and thereon allege, that Dr. Michelson substantially contributed to the development of the technology related to Infuse. Medtronic's own website fact sheet for Infuse gives credit to Dr. Michelson, stating that Infuse "Incorporates technology developed by Gary K. Michelson, M.D.," thus, Dr. Michelson's name was directly tied in with the Infuse on Medtronic's websites. Dr. Michelson's has numerous patents which involved the use of cages and spinal fusion implants, which are the core of Medtronic's business. Further, the LT-Cage must be utilized by any physician conducting a surgery utilizing INFUSE; as such, all plaintiffs herein had the LT-Cage implanted within their body.

f) U.S. Senators' Letters to MEDTRONIC Regarding to the Promotion and Marketing of INFUSE™.

i) September 30, 2008 Letter.

283. Despite the July 2006 Settlement with the DOJ, concerns regarding MEDTRONIC's off-label marketing activities and related payments to doctors continued.

284. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to MEDTRONIC noting that earlier in 2008, MEDTRONIC's outside counsel provided to the Special Committee on Aging a written account of MEDTRONIC's efforts to comply with the July 2006 Settlement Agreement it reached with the DOJ concerning allegations that MEDTRONIC and its subsidiary improperly compensated surgeons and physicians in connection with the INFUSE™ device.

285. Senator Kohl's letter expressed several concerns, including the following:

> That account also addressed the corporate integrity agreement (CIA) that MEDTRONIC and its subsidiary entered into with the Office of the Inspector General of the United States Department of

> Health and Human Services stemming from those same allegations. In that same letter to the Committee, MEDTRONIC and its subsidiary both denied that "improper payments were made to physicians in the first place (MEDTRONIC's agreement with DOJ does not contain any admission of liability), much less that improper payments 'have continued.' Consequently, it was with concern that I read recent articles, in the *Wall Street Journal* and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by MEDTRONIC to surgeons and physicians.
>
> These continuing allegations are directly relevant to the Committee's oversight of inappropriate physician compensation practices within the medical device industry. All of the major orthopedic device companies that settled with DOJ over such allegations were required to publicly reveal information related to their payments to physicians. MEDTRONIC's response to the Committee's initial inquiry articulated no specific reasons as to why MEDTRONIC has yet to voluntarily make the same disclosures.

286. In this letter, Senator Kohl requested both documentation of MEDTRONIC's efforts to comply with the July 2006 Settlement Agreement and interviews with corporate witnesses and documents "given the ongoing, serious concerns publicly raised regarding the integrity and transparency of MEDTRONIC's physician compensation practices."

287. Senator Kohl also asked MEDTRONIC to explain "the circumstances that led MEDTRONIC's former counsel to file suit against the company [alleging improper payments to physicians] and how that matter was subsequently settled."

288. Also on September 30, 2008, U.S. Senator Charles Grassley sent a similar letter to MEDTRONIC pertaining to the marketing of INFUSE™ and allegations of related kickbacks to physicians regarding the sale of INFUSE™, noting that:

> Last week, the *Wall Street Journal (WSJ)* reported on allegations of financial perks provided to doctors that included "entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in."[15] I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and questions.

[15] David Armstrong, "Lawsuit Says MEDTRONIC Gave Doctors Array of Perks," *Wall St. J.*, Sept. 25, 2008.

289. Senator Grassley went on to express his concern over the *Wall Street Journal*'s reports "that one of the incentives MEDTRONIC provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

290. This letter specifically addressed issues related to MEDTRONIC's marketing of INFUSE™:

> Fourth, earlier this month the WSJ reported on problems with off-label use of MEDTRONIC's INFUSE™. INFUSE™ is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that MEDTRONIC gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of INFUSE™. The allegations that MEDTRONIC has been disguising these consulting agreements as inducements or kickbacks for physicians to use INFUSE™ are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what if anything has changed since these reported events.

291. Senator Grassley, in his September 30, 2008 letter, also questioned why several lawsuits against MEDTRONIC pertaining to INFUSE™ remained under seal, and indicated that he would like to "better understand the status of these lawsuits and the procedural process that has led to the current situation."

ii) June 21, 2011 Letter.

292. The U.S. Senate Committee on Finance investigated whether MEDTRONIC has continued to misrepresent the adverse events that result from INFUSE™ and rhBMP-2, as well as the possibility that MEDTRONIC improperly influenced clinical trials and reporting regarding rhBMP-2.

293. On June 21, 2011, U.S. Senators Charles Grassley and Max Baucus sent another letter to MEDTRONIC on behalf of the Senate Committee on Finance requesting that MEDTRONIC produce documents and communications pertaining to "adverse postoperative events and/or medical complications" resulting from the use of rhBMP-2.[16] The letter also

[16] Letter from Grassley and Baucus (June 21, 2011), *available at*, http://finance.senate.gov/newsroom/chairman/release.

requests that MEDTRONIC provide "[a] detailed account of payments that MEDTRONIC made to all INFUSE™ clinical investigators."

294. In their June 21, 2011 letter, Senators Grassley and Baucus state: "We are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of INFUSE™ on behalf of MEDTRONIC were aware that INFUSE™, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to MEDTRONIC."

295. The letter further states: "We are also concerned that other severe side-effects of INFUSE™ and similar bone-growth products developed by MEDTRONIC may have been unreported or under-reported in clinical literature. Reports have linked INFUSE™ to potentially fatal swelling in the neck and throat, and radiating leg pain. Concerns have also been expressed about a potential link to cancer."

iii) **December 13, 2011 Letter.**

296. Senators Herb Kohl, Charles Grassley, and Richard Blumenthal wrote to MEDTRONIC again in December 2011 demanding more information from the company over adverse events caused by on-label and off-label use of INFUSE™. The letter noted that "your company has experienced safety issues, such as with your spine product INFUSE™."

297. The letter also demanded that MEDTRONIC explain whether or not it requires physicians who receive funds from MEDTRONIC to disclose those payments to their patients before the patients receive one of MEDTRONIC's medical devices and "If not, why not?"

298. This new letter requires that MEDTRONIC produce this information to the U.S. Senate's Special Committee on Aging by no later than January 23, 2012.

299. On information and belief, this continued investigation by a U.S. Senate committee suggests that MEDTRONIC has not changed its ways with regard to its illegal promotion of INFUSE™, despite signing the CIA and paying a $40 million fine to DOJ in 2006.

g) **June 2011 Issue of *The Spine Journal.***

300. In June 2011, the *Spine Journal*, a leading medical journal in the United States, published a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of rhBMP-2 (INFUSE™) in the spine.

301. This special edition reviewed thirteen peer-reviewed articles about rhBMP-2 by MEDTRONIC-sponsored authors, and concluded that these articles had inaccurately reported the safety of rhBMP-2 applications in the spine by underestimating its risks.

302. In an editorial summarizing the findings of this special issue, five prominent physicians, including spine surgeons at Stanford University Medical Center, wrote that the earlier industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2-related clinical adverse events." For example, the industry-sponsored articles omitted mention of indications from the earliest trials of inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of sterility and cancer risks associated with rhBMP-2, as reported in FDA documents and hearings. The trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review/publication shortfalls.

303. According to this editorial and several of the accompanying articles in the *Spine Journal*, the thirteen MEDTRONIC-funded articles reported only successful fusions and extremely low or nonexistent rates of complications with INFUSE™, which led to the growth of "off-label" use of INFUSE™ in lumbar fusion procedures. The articles "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths."

304. Contrary to the conclusions of the earlier MEDTRONIC-sponsored trials and articles, an article in this special issue of the *Spine Journal* suggested "an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach."

> Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early

> postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. *Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.* In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy."

Eugene J. Carragee, Eric L. Hurwitz & Bradley K. Weiner, *A Critical Review Of Recombinant Human Bone Morphogenetic Protein-2 Trials In Spinal Surgery: Emerging Safety Concerns And Lessons Learned, The Spine Journal* 11, 471-72 (2011) (emphasis added).

305. This article also reported that ten of the earlier industry-sponsored rhBMP-2 trials were funded in whole or in part by the manufacturer of rhBMP-2 (INFUSE™), MEDTRONIC. Furthermore, in twelve of these earlier studies, the median-known financial association between the authors and MEDTRONIC Inc. was approximately $12,000,000-$16,000,000 per study (range, $560,000-$23,500,000). *Id.* at 475.

306. The following are some of the other significant conclusions in these articles in the June 1, 2011 Issue of *The Spine Journal*:

a. Many of the risks now accepted have been known since a publication by Poynton and Lane in 2002, which listed overgrown and uncontrolled bone formation, osteoclast activity (graft subsidence, migration, loss of fixation etc.), local safety (inflammation, edema, wound problems, and infection), potential negative effect of BMPs on exposed dura and nerves (neurologic events, retrograde ejaculation, persistent bladder retention, early back pain, leg pain, radiculitis, functional loss, carcinogenicity). *However, it appears that these risks were ultimately washed out and marginalized by the wealth of positive data from industry-sponsored studies.*

b. A 2-year rhBMP-2 follow-up published by Burkus, et al., reported no adverse events. However, in a 6-year follow-up publication using the same subjects, the

authors contradict their earlier publication stating that there had been seven early adverse events associated with subsidence in the rhBMP-2 group, yet they were not reported in the two year follow-up.

c. In fact, on closer inspection of the Burkus studies, it was noted that all adverse events mentioned in the six-year follow-up had occurred within the first two years.

d. Furthermore, four of the adverse events required further surgery, and 22 additional surgeries for device failures occurred in the same rhBMP-2 group between 0-2 years after surgery according to the FDA summary, but were not specifically reported in the 2003 or 2004 studies, which were the same patients over the same time frame.

e. The estimates of rhBMP-2 safety from the original publications underestimated rhBMP-2-related adverse events of the product. In the small pilot studies, there were inadequate numbers to assess safety, but some suggestion of potential harm was seen in at least one study. In the larger trials, there is evidence in each trial that rhBMP-2 complications may be common and may be serious, but in each publication these were underreported.

f. The presence and magnitude of conflicts-of-interest and the potential for reporting bias were either not reported or were unclear in each of the original industry sponsored studies. Some of the conflicts-of-interest statements reported appeared to be vague, unintelligible, or were internally inconsistent.

g. The original estimates of ICBG (Iliac Crest Bone Graft, the pre-rhBMP-2 gold standard procedure for spinal fusion) harvesting morbidity were based on invalid assumptions and methodology. This in turn may have exaggerated the benefit or underestimated the morbidity of rhBMP-2 in the clinical situations tested.

h. The control group methods and techniques, as selected for both posterior approach methods (PLIF and PLF) were potentially handicapped by significant design bias against the controls.

i. In those studies for which other data sources have been made available on the same patient sets (either FDA documents or subsequent reporting of follow-up data), serious contradictory findings have emerged. Major complications, additional surgeries, neurologic/urologic injury, and major back/leg pain events were apparently observed but not reported in the original articles.

j. By falsely reporting perfect or near perfect safety, the original studies might have led others to widespread off-label use of the product with some potentially catastrophic outcomes. Revised estimates of adverse events are:

i. Posterior lumbar interbody fusion techniques: 25-50% risk of associated adverse events.

ii. Anterior lumbar interbody fusion: 10-15% risk of adverse events.

iii. Anterior cervical fusion: 40% greater risk of adverse events in the acute postoperative period including potentially life-threatening complications.

iv. Posterolateral fusions: equivalent or greater early postoperative risk of morbidity compared with ICBG harvesting for this dosage; 16-20% of rhBMP-2 subjects had adverse back and leg pain events, *a probable two to threefold increase in the first three months after surgery over control groups* (emphasis added).

h) <u>October 25, 2012 U.S. Senate Committee on Finance Report on Medtronic's Manipulation of the INFUSE™ Studies and Close Financial Ties with Researchers</u>

306. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into MEDTRONIC, which revealed questionable ties between the company and its physician "Opinion Leader" consultants tasked with testing and reviewing INFUSE™. Without public disclosure of their roles, MEDTRONIC employees collaborated with the physician authors to edit – and in some cases, write – segments of published studies on INFUSE™. The studies may have inaccurately represented INFUSE™'s risks and may have overemphasized the

side effects of prior more traditional treatments. The Senate report found that MEDTRONIC also maintained significant, previously-undisclosed financial ties with the physicians who authored the early studies on INFUSE™, making $210 million in payments to physicians over a 15-year period.

307. "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has," Senator Baucus said. "Patients everywhere will be better served by a more open, honest system without this kind of collusion."

308. "These findings emphasize the value of the Grassley-Kohl Physician Payments Sunshine Act, which will result in public disclosure of industry payments to physicians starting next year. The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and studies they feature," Grassley said. "These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

309. The report released on October 25, 2012 by Senators Baucus and Grassley on behalf of the U.S. Senate Finance Committee – which has sole jurisdiction over Medicare and Medicaid – was the product of an investigation they began in June 2011.[17] The major findings of the investigation include:

a. MEDTRONIC was involved in drafting, editing, and shaping the content of medical journal articles on INFUSE™ authored by its physician consultants who received significant amounts of money through royalties and consulting fees from MEDTRONIC. The company's significant role in authoring or substantively editing

[17] The Senate's full report is available online at: http://www.finance.senate.gov/newsroom/chairman/download/?id=e54db17c-a475-4948-bd81-69c8740c6aaf. In the interest of brevity, Plaintiff has not attached the full 2,315 page report.

these articles was not disclosed in the published articles. Medical journals should ensure any industry role in drafting articles or contributions to authors be fully disclosed.

b. MEDTRONIC paid a total of approximately $210 million to physician authors of MEDTRONIC-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a MEDTRONIC employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with INFUSE™ in a 2005 *Journal of Bone and Joint Surgery* article.

d. MEDTRONIC officials inserted language into studies that promoted INFUSE™ as a better technique than an alternative by emphasizing the pain associated with the alternative.

i) Further Evidence of MEDTRONIC's Off-label Promotion.

310. MEDTRONIC's knowledge and promotion of off-label use of INFUSE™ is further evidenced by comparing sales of the rhBMP-2 component to the sales of the LT-Cage™ component (both components are required pursuant to FDA approval). On information and belief, MEDTRONIC sells the rhBMP-2 component separately from the LT-Cage™ in order to illegally and improperly promote off-label uses of INFUSE™ in procedures in which the LT-Cage™ is not used. As a result, sales of the rhBMP-2 component are and were at all relevant times far larger than sales of the LT-Cage™ component, despite FDA requirements that both be used according to the product's labeling; i.e. that the entire medical device (rhBMP-2 and the LT-Cage™) be used in the procedure.

311. As described in detail above and throughout this Complaint, therefore, MEDTRONIC's off-label promotion of INFUSE™ was not truthful. Instead, MEDTRONIC's off-label promotion of INFUSE™ was false and misleading. "Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection." *United States v. Caronia*, No. 09-5006-cr, 2012 U.S. App. LEXIS 24831, at *39, n. 11 (2d Cir. Dec. 3, 2012).

312. MEDTRONIC's aggressive off-label promotion described above created the conditions for widespread acceptance by spine surgeons of the off-label uses of INFUSE™ after the 2002 PMA approval, and MEDTRONIC's violations of federal law described above (which parallel Plaintiff's state-law tort claims) directly caused or significantly contributed to the widespread off-label use of INFUSE™ generally, and also specifically with respect to Plaintiff. In particular, MEDTRONIC's off-label promotion activities and failure to report adverse events caused spine surgeons, including Plaintiff's surgeon to use INFUSE™ in dangerous off-label procedures.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION -- MANUFACTURING DEFECT

(Against All Defendants and Does 1-100)

Plaintiffs repeat and realleges every allegation set forth above as if fully set forth herein.

313. Plaintiffs' use of Infuse and the LT-Cage™ off-label in spinal fusion surgery was a reasonably foreseeable use, marketed and promoted by Defendants.

314. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson placed Infuse the LT-Cage™ on the market in the ordinary course of business and knew Infuse was to be used without inspection for defects.

315. Defendants Wyeth and Pfizer are responsible for the manufacture, marketing, and distribution of INFUSE and the LT-Cage on the west coast of the United States, including, but not limited to, California.

316. The Infuse drug implanted into Plaintiffs was defective, as evidenced by its failure to comply with the manufacturing specifications required by Infuse's (and the LT-Cage's approval, which must be included with INFUSE) Premarket Approval and Current Good Manufacturing Practices under the FDCA.

317. The drug was defective when it left Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's hands. Upon information and belief, Plaintiffs' physicians at all times assembled and inserted the drug in accordance with proper procedure and was received in accordance with normal shipping and storage procedures from the

manufacturers. Despite their conformance with procedure, the use of the drug resulted in nerve compression and severe, chronic, ongoing pain. As a result, the drug proximately caused Plaintiffs' injuries and damages in a sum in excess of the jurisdictional minimum of this Court.

SECOND CAUSE OF ACTION
FAILURE TO WARN

(Against All Defendants and Does 1-100)

318. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

319. Plaintiffs allege Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson had an established duty to warn of the dangers in using Infuse and the LT-Cage™ for off-label purposes which makes Infuse unreasonably dangerous to use without such warning. As alleged, Defendants were aware of the dangers generally known to the scientific community at the time they manufactured and distributed Infuse.

320. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson failed to provide warning of the dangers of using Infuse and the LT-Cage™ off-label, specifically failing to warn Plaintiffs and their treaters regarding known dangers including the danger of spinal immobility and nerve damage occurring, as alleged in Applicable FDA Regulations Paragraph 12(c). Defendants Medtroinc, the Medtronic managers, and Dr. Gary K. Michelson's failure to warn Plaintiffs of the dangers of using Infuse off-label caused themto undergo an implantation of Infuse and proximately caused them to suffer injuries alleged and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

THIRD CAUSE OF ACTION -DESIGN DEFECT

(Against All Defendants and Does 1-100)

321. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

322. Plaintiffs allege that Infuse, when used off-label, was designed in a materially defective manner.

323. Design defect claims for uses of Infuse and the LT-Cage™ off-label are not pre-empted by 21 U.S.C. § 360k(a) nor impliedly pre-empted under *Buckman Co v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), because Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson actively and illegally promoted and marketed Infuse's off-label use in violation of its Premarket Approval and because there is a right of action for strict liability in defective design of a product separate from the FDCA's causes of action in California.

324. As alleged in Applicable FDA Regulations Paragraphs 10 through 11, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson violated the FDCA by introducing and promoting an adulterated product. Accordingly, this allegation "parallels" the FDA regulation in accordance with § 360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

325. Further, the off-label use of Infuse was defective in design based on California's strict liability under its theory of products liability.

326. Plaintiffs allege herein, Infuse was used in an intended or reasonably foreseeable manner. This off-label usage of Infuse was not only reasonably foreseeable, but explicitly intended by the promotion and marketing, by Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson.

327. Infuse and the LT-Cage was in a defective condition when it left Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's hands. As alleged, Infuse failed, resulting in injury.

328. Infuse and the LT-Cage™ caused bone growth in Plaintiffs, leading to additional injuries. Infuse and the LT-Cage™ is the proximate cause of Plaintiffs' injuries and damages, as alleged herein and additional and general damages in a sum in excess of the jurisdictional minimum of this Court.

FOURTH CAUSE OF ACTION -- NEGLIGENCE

(Against All Defendants And Does 1-100)

329. Plaintiffs repeat and reallegs every allegation set forth above as if fully set forth herein.

330. A proximate cause of Plaintiffs injuries and damage is the negligence and misrepresentations of Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson through their agents, sales representatives/consultants, paid Key Opinion Leaders, servants and/or employees acting within the course and scope of their employment, negligently, carelessly and recklessly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing INFUSE and the LT-Cage™, and including among other things:

i. Negligently and carelessly engaging in the illegal off-label promotion of INFUSE and the LT-Cage™ by recommending to physicians, including Plaintiffs Physicians, and instructing them to use it in procedures for which it had not been approved;

ii. Negligently, carelessly and recklessly promoting the off-label use of INFUSE and the LT-Cage™ by instructing, promoting and directing the use of the product in cervical and lumbar fusion procedures that had not been approved by the FDA;

iii. Negligently, carelessly and recklessly failing to disclose to physicians that the promoted off-label use of INFUSE and the LT-Cage™ can result in serious side effects;

iv. Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with the off-label use of INFUSE and the LT-Cage™;

v. Negligently, carelessly and recklessly representing that the off-label use of INFUSE and the LT-Cage™ was safe when, in fact, it was unsafe;

vi. Negligently, carelessly and recklessly promoting INFUSE AND THE LT-CAGE™ and the LT-Cage™ beyond the narrow and limited uses for which it was approved;

vii. Negligently, carelessly and recklessly failing to adequately warn the medical community, the general public, plaintiffs surgeon and plaintiff of the dangers, contra-indications, and side effects from the off-label use of INFUSE and the LT-CAGE™ ;

viii. Negligently, carelessly and recklessly failing to act as a reasonably prudent drug manufacturer.

ix. Commissioning studies which misrepresented the risks associated with off-label use of INFUSE and the LT-CAGE™;

x. Compensating the authors of the above studies monetarily for their opinions;

xi. Other violations according to proof.

331. Before Plaintiffs were given INFUSE and the LT-CAGE™ through an off-label cervical or lumbar fusion procedure, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, based upon the state of knowledge as it existed at the time, knew or should have known that such a use could be dangerous and unsafe, and knew or should have known that such a use could result in severe, chronic, ongoing numbness throughout the body, acute pressure and headaches, and other serious side effects.

332. Failure to comply with the above FDCA and PMA requirements amounted to a breach of the duties owed to Plaintiffs. Such acts also constitute adulteration, misbranding, or both under FDCA, 21 U.S.C. §§321, *et seq.*, and therefore subject Defendants Medtroinc, the Medtronic managers, and Wyeth, Pfizer Dr. Gary K. Michelson, to civil liability for all damages arising therefrom, under the theory of negligence per se.

333. Had Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson complied with their duties to the FDA and as described under the FDCA, the

necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action.

334. Plaintiffs, having had INFUSE implanted into their spines or bodies, are within the class of persons that the above-referenced federal statutes and regulations are designed to protect, and their injuries are the type of harm these statutes and regulations are designed to prevent.

335. As a direct and proximate result of the acts and conduct of Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson Plaintiffs were injured in their health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to their damage in an amount in excess of the jurisdictional minimum of the Court.

336. As a further direct and proximate result of the acts and conduct of the Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, Plaintiffs have lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

337. As a further direct and proximate result of the acts and conduct of Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, Plaintiffs have incurred medical, hospital and related expenses and, on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

FIFTH CAUSE OF ACTION -- FRAUD

(Against All Defendants And Does 1-10)

338. Plaintiffs repeat, reallege, and incorporate herein by this reference, all of the preceding allegations as though set forth in full.

339. As a pharmaceutical company, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, had an affirmative continuing duty to warn the public and medical community regarding risks it knew, learned, or should have known about associated with its medical devices and pharmaceutical products, and had an affirmative, continuing duty to the FDA regarding the same.

340. Had Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action

341. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson concealed adverse information and provided inaccurate or misleading information which was material to treating surgeons' treatment decisions, which misled surgeons and patients who were relying on those surgeons' professional judgment, including Plaintiff and her treating surgeon. This misleading information, along with omissions of material facts related to Infuse's (and the LT-Cage's) safety and effectiveness, caused health care providers, patients and the general public, including Plaintiff and her surgeons, to be misled about Infuse's (and the LT-Cage's) risks and benefits and deprived surgeons from making a proper risk/benefit assessment as to the use and off-label use of Infuse.

342. Through internal adverse event reports, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson knew that the off-label use of Infuse (and the LT-Cage) was not effective and could lead to serious side effects, including but not limited, to severe, chronic, and ongoing numbness in the body and acute pressure and headaches, and other serious side effects. Defendants failed to take any measures whatsoever to alert surgeons or the public regarding these risks and instead continued to promote the off-label use of Infuse as safe and effective.

343. Plaintiffs are informed and believe and based thereon alleges that, despite knowing that the off-label promotion of Infuse and the LT-Cage was illegal, Defendants

Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, through its sales representatives/consultants and Key Opinion Leaders, promoted the off-label use of Infuse to Plaintiff's physicians and concealed that the off-label use of Infuse could result in unwanted bone growth and other serious side effects.

344. Plaintiffs are informed and believe and based thereon alleges that, when the above representations and/or omissions were made by Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Defendants Medtroinc, the Medtronic managers, and Dr. Gary K. Michelson, with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing surgeons and hospitals to use and recommend the off-label use of Infuse.

345. Plaintiffs are informed and believe and based thereon alleges that, at the time the aforesaid representations and/or omissions were made by Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, Plaintiffs and their medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon Defendants' assertions, promulgated through aggressive sales tactics as set forth herein, that the off-label use of Infuse and the LT-Cage was safe and effective when, in fact, it was neither.

346. Plaintiffs are informed and believe and based thereon alleges that, in direct and indirect reliance upon said representations and/or omissions, Plaintiffs physicians used Infuse in an off-label fusion procedure.

347. Had Plaintiffs' physicians been made aware of the inefficacy and serious risks associated with such use, she would not have used it.

348. Had Plaintiffs known of the actual dangers of and inefficacy of the off-label use of Infuse, she would not have consented to its use in her surgery.

349. Plaintiffs are informed and believes and based thereon alleges that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's motive in

failing to advise surgeons and the medical community of these risks and inefficacies was for financial gain and fear that, if it provided proper and adequate information, Infuse would lose sales and market share.

350. Plaintiffs are informed and believes and based thereon alleges that, at all times herein mentioned, the actions of Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson, their agents, servants, and/or employees was wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiffs in particular, and to the public generally, in that Defendants did willfully and knowingly promote the off-label use of Infuse with the specific knowledge that it would be used by surgeons without adequate instructions and without adequate knowledge regarding its efficacy, risks and side effects.

351. Despite its specific knowledge regarding risks as set forth above, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson deliberately recommended the off-label use of Infuse and the LT-cage and promoted it as being safe and effective.

352. Plaintiffs are informed and believe and based thereon alleges that, at all times relevant herein, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's conduct was malicious, fraudulent, and oppressive toward Plaintiff in particular and the public generally, and Defendants Medtroinc, the Medtronic managers, and Dr. Gary K. Michelson conducted itself in a willful, wanton, and reckless manner by actively violating federal regulations.

353. In doing the things aforementioned, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

SIXTH CAUSE OF ACTION -- INTENTIONAL MISREPRESENTATION

(Against All Defendants And Does 1-100)

354. Plaintiffs repeat, reallege, and incorporate herein by this reference, all of the preceding allegations as though set forth in full.

355. In connection with the marketing and sales of Infuse, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson made misrepresentations of material facts regarding the merchantability and safety of Infuse for off-label use. As alleged in Applicable FDA Regulations Paragraphs 14 through 20, Defendants Medtroinc, and Dr. Gary K. Michelson reported findings with significantly less incidences of complications than were reported in the data supporting the findings and misrepresented the independence of the authors of the reports on Infuse's (and the LT-Cage's) off-label use.

356. Had the Medtronic Defendants and Dr.Gary Michelson complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action

357. All of the Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson have been paid or paid sham "consulting fees" in 2006. None of these Defendant Medtronic Managers performed bona fide consulting services for Medtronic. All of these payments constitute kickbacks for purchases made or effected by each physician and/or for the agreement to perform unlawful promotional activities for on-label and off-label sales of Medtronic products.

358. As reported by the United States Senate Committee on Finance, there were several Medtronic employees/agents who provided inaccurate or misleading information. Dr. John Kenneth Burkus, a Medtronic consultant, admitted via email that he expected a Medtronic study to be endorsed by authors who did not author the article. Julie Bearcraft, a Medtronic employee, asked that reports of adverse events associated with Infuse Bone Graft be omitted. Rick Treharne, a Medtronic employee, admitted via email that he helped author a spinal surgery study, even though he is not a medical doctor. Bill Martin, a Medtronic employee, stated via email that off-label surgeries should not be discouraged.

359. In agreeing to undergo a procedure whereby Infuse Bone Graft (along with the LT-Cage) was implanted, Plaintiffs justifiably relied on such misrepresentations by Medtronic Defendants, Wyeth, Pfizer, Dr. Gary Michelson, and the referenced Medtronic employees/agents - specifically the Medtronic sales representative who was present in Plaintiffs' operating room and orchestrated Plaintiffs' surgery.

360. In agreeing to undergo a procedure whereby Infuse (along with the LT-Cage) was implanted, Plaintiffs justifiably relied on such misrepresentations by the Medtronic Defendants, Wyeth, Pfizer, Dr. Gary Michelson.

361. Said reliance on the misrepresentations has caused, now causes, and will continue to cause significant physical harm, discomfort, damages, and injuries to Plaintiff as alleged and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

SEVENTH CAUSE OF ACTION -- CALIFORNIA UNFAIR COMPETITION LAW

(Bus. & Prof. Code § 17200 et seq.)

(Against All Defendants And Does 1-100)

362. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

363. Under California Unfair Competition Law ("UCL"), Business & Professions Code § 17200, et seq., Defendants Medtroinc, the Medtronic managers, Pfizer, Wyeth and Dr. Gary K. Michelson owed a duty to Plaintiffs not to provide unfair, deceptive, untrue, or misleading advertising related to the safety and efficiency of its Infuse drug and a duty not to commit unlawful, fraudulent, or unfair business acts or practices.

364. Defendants Medtroinc, the Medtronic managers, Pfizer, Wyeth and Dr. Gary K. Michelson violated this duty and committed unfair business acts under the UCL by proactively marketing Infuse, combined with the LT-Cage, for off-label usage, including with spinal fusion surgery in violation of FDCA regulations and Infuse's Premarket Approval. In addition, Defendants Medtroinc, the Medtronic managers, Pfizer, Wyeth and Dr. Gary K. Michelson violated its duty and committed unfair business acts under the UCL by misrepresenting to

Plaintiffs' physician the risks associated with such usage. As a direct and proximate consequence of Defendant Medtroinc, the Medtronic managers, Pfizer, Wyeth and Dr. Gary K. Michelson's acts, omissions, and misrepresentations as described herein and Plaintiffs' physicians' reliance on the same, Plaintiffs were harmed.

365. Plaintiffs are informed and believe that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's conduct is not just limited to its marketing to Plaintiffs' physician and Plaintiffs, but rather is part of a design, pattern, practice, and business practice designed to injure and/or mislead and/or defraud customers, including Plaintiffs' physician and Plaintiffs, to purchase and use its Infuse drug.

366. Plaintiffs are informed and believe that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's conduct and acts of unfair competition are ongoing and present a continuing threat of harm to the general public.

367. Plaintiffs are informed and believe that v have profited by means of its wrongful conduct. This profit amounts to "ill-gotten gain."

368. Plaintiffs are informed and believe that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson had specific knowledge of the unusually high rate of off-label Infuse use, that the drugs were not manufactured, tested, or validated in accordance with the FDCA and Infuse's Premarket Approval and that the drugs were adulterated when they left Defendant's control.

369. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson conduct, as set forth herein, was done with oppression, fraud, and/or malice, and in conscious, willful, and reckless disregard of Plaintiffs' health, safety, and welfare. Accordingly, Plaintiffs are to recover exemplary and punitive damages and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

EIGHTH CAUSE OF ACTION -- BREACH OF EXPRESS AND IMPLIED WARRANTIES

(Against All Defendants And Does 1-100)

370. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

371. At all times herein mentioned, Defendants Medtroinc, the Medtronic managers, and Wyeth, Pfizer Dr. Gary K. Michelson utilized journal articles, advertising media, sales representatives and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of the Infuse Bone Graft, combined with the LT-Cage, and expressly and impliedly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in posterior procedures was safe and effective.

372. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson knew or, in the exercise of reasonable diligence, should have known that such off-label uses had the serious side effects set forth herein.

373. Plaintiffs are informed and believes and based thereon alleges that Plaintiffs' treating surgeons, doctors, and other physicians and medical professionals, relied on Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson's express and implied warranty representations regarding the safety and efficacy of off-label use of Infuse Bone Graft combined with the LT-Cage, but such off-label uses were not effective, safe, and proper for the use as warranted in that such it failed, migrated, lead to unwanted bone growth and was dangerous when put to its promoted use.

374. Plaintiffs are informed and believe and based thereon allege that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson breached the implied warranties of merchantability and fitness because the Infuse Bone Graft (which includes the LT-Cage) is unsafe for the promoted uses, is not merchantable, is unfit for its promoted use when sold, is unfit for the purpose for which it was sold, and/or is not adequately packaged and labeled, and did not reasonably conform to the promises or affirmations of fact made by Defendants.

NINTH CAUSE OF ACTION -- NEGLIGENCE PER SE

(Against All Defendants And Does 1-100)

375. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

376. Defendants violated applicable federal statutes and regulations relating to medical devices.

377. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson violations of these federal statutes and regulations caused Plaintiffs' injuries.

378. Plaintiffs' injuries resulted from an occurrence in which the federal statutes and regulations were designed to prevent.

379. Had Medtronic Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action

380. Plaintiffs are of the class of persons whom these federal statutes and regulations were meant to protect.

381. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer and Dr. Gary K. Michelson violations of these statutes and regulations constitute negligence per se.

382. As a proximate result of the concealment or suppression of the material facts, Plaintiffs sustained injuries and damages alleged herein and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

TENTH CAUSE OF ACTION -- STRICT LIABILITY

(Against All Defendants And Does 1-100)

383. Plaintiffs repeat and reallege every allegation set forth above, as if they fully set forth herein.

384. At all times herein mentioned, Defendants Medtroinc, Wyeth, Pfizer, and Dr. Gary K. Michelson placed Infuse on the market.

385. At all times herein mentioned, the off-label use of Infuse (combined with the LT-Cage) in a cervical or lumbar fusion procedure was defective, unsafe, and ineffective, and

Defendants Medtroinc, Wyeth, Pfizer, and Dr. Gary K. Michelson knew or should have known that it was unsafe and ineffective when used in an off-label manner as promoted, instructed and supplied by Defendants Medtroinc, Wyeth, Pfizer, and Dr. Gary K. Michelson, and as utilized in Plaintiffs' surgery.

386. Had Medtronic Defendants complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action.

387. At all times herein mentioned, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer, and Dr. Gary K. Michelson had specific knowledge of the risks involved in the off-label use of Infuse (combined with the LT-Cage) when used in surgery.

388. At all times herein mentioned, Plaintiffs relied upon the misrepresentations of Defendants, in and utilized the product in an off-label manner as promoted and instructed by Defendants.

389. At all times herein mentioned, the off-label use of Infuse (combined with the LT-Cage) produced serious side effects, including unwanted bone growth and migration, and Defendants knew or should have known that said usage could be unsafe because of said side effects.

390. Plaintiffs were given Infuse in a manner that had been illegally promoted and intended by Defendants.

391. Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer, and Dr. Gary K. Michelson promoted the off-label use of Infuse with the knowledge of its risk to patients.

392. The off-label use of Infuse (combined with the LT-Cage), as given to Plaintiffs was ineffective, defective, and dangerous when manufactured, designed, promoted, and instructed by Defendants, who is strictly liable for the injuries arising from its use.

393. The risks attendant to the off-label use of Infuse (combined with the LT-Cage) greatly outweighed the benefits to be expected from said use as promoted by Defendants.

394. The off-label use of Infuse (combined with the LT-Cage) failed to perform in a manner that a reasonable consumer would expect it to perform.

395. Plaintiffs are informed and believe, and thereon allege, that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer, and Dr. Gary K. Michelson knew that Infuse, when used off-label in the manner described above and as promoted and instructed by Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer, and Dr. Gary K. Michelson, was defective and dangerous in the manner hereinbefore described; that Defendants knew that, because said use was dangerous and defective when so used off-label, the product could not be safely used for the purpose intended; that Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer, and Dr. Gary K. Michelson, knowing that said product when used off-label was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Plaintiffs' safety, when it placed the product on the market without warning of the defect, and knew when so placed that it would be used without inspection for defect when so used.

396. By placing said product on the market and promoting said off-label use, Defendants Medtroinc, the Medtronic managers, Wyeth, Pfizer, and Dr. Gary K. Michelson impliedly represented it was safe for the purpose intended, and intended that doctors and patients in the general public should rely on their misrepresentations. Plaintiff and their doctors did rely on each of said misrepresentations, all to their damage as hereinabove alleged. In doing the things aforementioned, Defendants are guilty of malice, oppression, and fraud, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

ELEVENTH CAUSE OF ACTION

Punitive Damages

396. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

397. At all times herein referenced, officers, directors, and managing agents of MEDTRONIC knew, and were aware, and concealed, hid, and/or otherwise downplayed the true risks of non-FDA approved off-label uses of its product INFUSE™ (which includes the bone Morphogenetic Protein rhBMP-2, in addition to the LT-Cage).

398. At all times herein referenced, officers, directors, and managing agents of MEDTRONIC knew, and were aware, that numerous people had ectopic bone formation, radiculitis, osteolysis, cage migration, and worse overall outcomes as a result of non-FDA approved off-label uses of its product INFUSE™.

399. The MEDTRONIC defendants designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, distributed, wholesaled, and sold INFUSE™, a product which said Defendants knew to be dangerous and unsafe for the purpose for which they intended it to be used, namely, as a bio-engineering bone draft device in spinal fusion surgeries.

400. At all times herein mentioned, prior to and at the time that the MEDTRONIC Defendants design, manufactured, promoted, marketed, supplied, distributed, and/or sold INFUSE™ to Plaintiff, and prior to the time that said product was used, the MEDTRONIC Defendants knew, or should have known, that INFUSE™ was defectively designed and manufactured, that it had extremely dangerous properties and defects, and that it had defects which would cause serious injuries and damage to users of said product, thereby threatening the life and health of the users. Further, at all times, the MEDTRONIC Defendants knew that INFUSE™ had caused serious injuries and damage to other members of the public.

401. At all times herein mentioned, the MEDTRONIC Defendants, despite the actual knowledge described hereinabove, intentionally suppressed the aforementioned complaints, actively concealed and downplayed the risks associated with INFUSE™, actively promoted the illegal, off-label use of INFUSE™, failed to warn Plaintiffs and the medical community of the true risks associated with INFUSE™, and saturated the scientific and medical literature with

biased, industry-funded studies to conceal the true risks of INFUSE™, and otherwise failed to warn Plaintiff, the medical community, and/or the general public.

402. At all times herein mentioned, the MEDTRONIC Defendants had actual knowledge of the facts hereinabove alleged demonstrating that serious injury to patients in which INFUSE™ was implanted, particularly in an off-label manner such as the fusion surgery Plaintiffs underwent. The MEDTRONIC Defendants nevertheless deliberately suppressed, concealed, downplayed, and/or otherwise hid any information demonstrating the true risks associated with INFUSE™ from Plaintiffs, the medical community, and/or the general public. Instead, the MEDTRONIC Defendants continued to actively promote the illegal, off-label use of INFUSE™ to spine surgeons in an effort to maintain INFUSE™'s enormous profitability.

403. As a legal and proximate result of the MEDTRONIC Defendants' conduct, as herein alleged, Plaintiffs sustained the injuries and damages set forth above.

404. The MEDTRONIC Defendants' conduct and omissions, as set forth above, in allowing such an extremely dangerous product to be used by members of the general public, including Plaintiffs, constitutes fraud, malice and oppression toward Plaintiffs and others, and a conscious disregard of the safety of Plaintiffs and others.

405. Plaintiffs are therefore entitled to exemplary or punitive damages, which would serve to punish the Defendants and to deter wrongful conduct in the future.

406. Plaintiffs are therefore entitled to judgment against the MEDTRONIC Defendants as hereinafter set forth

DEMAND FOR JURY TRIAL

407. Plaintiffs hereby demand a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

408. For general damages in a sum exceeding this Court's jurisdictional minimum;

409. For specific damages according to proof;

410. For economic and non-economic damages in a sum exceeding this Court's jurisdictional minimum;

411. For punitive and exemplary damages according to proof;

412. For pre-judgment interest and post-judgment interest as allowed by law;

413. For the costs of suit herein incurred; and

414. For medical and related expenses according to proof;

415. For loss of earnings according to proof;

416. For exemplary and punitive damages according to proof;

417. For cost of suit herein;

418. For injunctive relief, enjoining Defendants from the acts of unfair competition and untrue and misleading advertising;

419. For a disgorgement of profits, according to proof; and

420. For such other and further relief as the Court may deem just and proper, including prejudgment interest.

Respectfully submitted,

DATED: December 18, 2013

NAPOLI BERN RIPKA SHKOLNIK & ASSOC., LLP
Attorneys for Plaintiffs

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PROOF OF SERVICE

STATE OF CALIFORNIA)
)
COUNTY OF ORANGE)

I am employed in the County of Orange, State of California. I am over eighteen years of age and not a party to the within action; my business address is 111 Corporate Drive, Suite 225, Ladera Ranch, California 92694.

On the date set forth below, I served the foregoing document(s) described as:

AMENDED COMPLANT

On all interested parties in this action addressed as follows:

SEE ATTACHED SERVICE LIST

[X] BY MAIL: By placing a true copy thereof in a sealed envelope addressed as above, and placing it for collection and mailing following ordinary business practices. I am readily familiar with the firm's practice of collection and processing correspondence, pleadings, and other matters for mailing with the United States Postal service on that same day with postage thereon fully prepaid at Ladera Ranch, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

[ ] BY FAX: I transmitted a copy of the foregoing document(s) via telecopier to the facsimile numbers of the addressee(s), and the transmission was reported as complete and without error.

[ ] BY OVERNIGHT COURIER: I transmitted a copy of the foregoing document(s) via e-mail to the addressee(s).

I declare under penalty of perjury, under the laws of the State of California that the above is true and correct. Executed this 18th day of December, 2013, at Ladera Ranch, California.

RYAN HENRY

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF LOS ANGELES

RICHARD PLUMMER, JOHNNY BALLINGER, TIMERY UEBBING, TERRY MARTINEZ, TABATHIA GATES, SHARON WHITE, SARA MCMILLAN, ROSILAND SPENCER, RONDA HOULE, NINA VINCENT, MICHAEL MCMILLAN, MAUREEN JACQUES, LORI SHOULDERS, LEONARD HUNTER, JIMMY WEEKS, ISABEL BUCKHOLDT, DYLAN WEST, AUDRA GUERRETTAZ, HASKELL CROFT, DAWN TRUAX, SHANNON COMPSTON, DEREK DAVIS, NORVEL DICKENS, GANA BRETT, JIMMY HENDRICH, JEFFERY HINES, BRENDA LANDIS, PATRICK MCCOY, JOHN MANCUSO, MARSHA MORRIS, ANTHONY NORMIL, PIO EMILIA, NANCY SCHREIBER, WILLIE STANBERRY JR., DOUGLAS PRESTIDGE, MARYANNE WAGNER, BYOTHA THOMAS, PATRICIA SHEPARD, ROSEMARY PENTON, NICHOLAS SCHULTZ, MARY TIMMONS, MELODIE WARD, CYNTHIA GIBSON, SHEILA GOODMAN-GILBERT, KRISTAL REED, PENNY ROMERO, SHIRLEY HANEY, AND KAREN SAPPINGTON, Plaintiffs, vs.	Case No. BC528729 COMPLAINT FOR DAMAGES JURY TRIAL DEMAND BY FAX 1. Products Liability – Manufacturing Defect 2. Failure to Warn 3. Strict Products Liability – Design Defect 4. Strict Products Liability – Negligence 5. Fraud 6. Intentional Misrepresentation 7. California Unfair Competition Law 8. Breach of Express and Implied Warranties 9. Negligence per se 10. Strict Liability 11. Punitive Damages

MEDTRONIC, INC. MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC VERTELINK, INC., WYETH INC., WYETH PHARMACEUTICALS, INC., PFIZER, INC., DR. GARY K. MICHELSON, ALEX BOLANOS, KEVIN BRADLEY, DEBBIE PAGACH, MARAL AMIRI, and DOES 1 THROUGH 100, inclusive, Defendants.	

COMES NOW Plaintiffs, and each of them, and complain and allege against MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC VERTELINK, INC., (collectively referred to as "MEDTRONIC" or "MEDTRONIC DEFENDANTS"), WYETH INC., WYETH PHARMACEUTICALS, INC., PFIZER, INC., DR. GARY K. MICHELSON, ALEX BOLANOS, KEVIN BRADLEY, DEBBIE PAGACH, MARAL AMIRI, and DOES 1 THROUGH 100, each of them as follows:

COMPLAINT

GENERAL ALLEGATIONS

1. This case involves a number of spinal surgeries in which a bioengineered, liquid, bone graft device, INFUSE™ Bone Graft ("INFUSE™"), was implanted in Plaintiffs in an off-label manner.

2. The FDA classifies INFUSE ™ as a medical device. The INFUSE Bone Graft and LT-Cage (collectively known as "Infuse") is manufactured, promoted, marketed, and distributed by Defendants Medtronic, Medtronic Sofamor Danek and Medtronic Vertelink, and Wyeth, a subsidiary of Pfizer, and promoted, invented, marketed and designed, in part, by Dr. Gary Karlin Michelson.

3. INFUSE™ is used in spinal fusion surgeries, and its purpose is to fuse vertebrae of the spine together and yield the same result as implanting a patient's own bone or cadaver bone, thereby obviating the need to harvest bone from the patient's own hip and maximizing the procedure's success rate. As noted above, Infuse consists of two separate components. One component is a drug known as recombinant human bone morphogenetic protein-2 ("rhBMP-2"), which was developed and sold by Wyeth, a wholly owned subsidiary of Pfizer; this drug is placed on a collagen sponge, and delivered to health care providers, and the Plaintiff's physicians, in a separate package. The second component, also delivered in a separate package, is a metal cage device (the "LT-cage"), which was invented, in part, by Dr. Michelson. This cage acts as a scaffold to house the sponge that contains rhBMP-2.

4. This case involves a number of spinal fusion surgeries in which INFUSE™ was used in an *off-label* (e.g., not approved by the FDA) manner for a spinal fusion. The FDA approved INFUSE™ *only* for lumbar surgery that is performed through the abdomen (anterior approach) – and for some tibia fractures and specific dental surgeries irrelevant to this case. Further, the FDA approved INFUSE™ for anterior lumbar surgery only when INFUSE™ is used *in combination with* an "LT-Cage™," a hollow metal cylinder used to insert the INFUSE™ into the spine. The FDA did *not* approve INFUSE™ for use in cervical spine surgery or any non-anterior approach to lumbar surgery, such as through the back or side of the body (posterior and lateral approaches, respectively). Therefore, all cervical spine surgeries, many lumbar surgeries, and any INFUSE™ back surgery without using an LT-Cage™ are off-label uses.

5. Despite this lack of FDA approval and the FDA's explicit concerns about the dangers of off-label uses to patients, MEDTRONIC improperly promoted INFUSE™ to be used

off-label for posterior lumbar spine fusions, cervical spine fusions, and spine fusions without an LT-Cage™.

6. Patients' spine surgeons, including Plaintiffs' surgeons, were persuaded by MEDTRONIC and MEDTRONIC's consultant "opinion leaders," who are paid physician promoters, to expand their INFUSE™ use to off-label uses, such as posterior lumbar fusions and cervical spine fusions.

7. At all times relevant to this action, all persons acting on behalf of MEDTRONIC were employees and/or agents with actual, implied, or inherent authority to act on behalf of MEDTRONIC. MEDTRONIC approved or ratified all such actions of these employees and/or agents.

8. INFUSE™, when used off-label, can cause severe injuries to the patient, including INFUSE™-induced bone overgrowth and other complications that often necessitate painful, risky, and costly revision surgeries that might not cure the problems that the INFUSE™ caused.

9. This uncontrolled bone growth (also known as "ectopic" or "exuberant" bone growth) can compress or severely damage the surrounding neurologic structures in the spine, and bone can grow onto or around the spinal cord or spinal nerve roots. When this excessive bone growth compresses the nerves, the patient can experience, among other adverse events, intractable pain, paralysis, spasms, and the need for revision surgery.

10. INFUSE™, when used off-label, can cause or contribute to other serious injuries and complications, including extreme inflammatory reactions, chronic radiculitis, retrograde ejaculation, sterility, osteolysis (bone resorption), displacement or migration of the spacer cage, pseudoarthrosis, and worse overall outcomes.

11. Notwithstanding overwhelming and substantial evidence (including MEDTRONIC-sponsored studies) demonstrating these increased risks of adverse reactions from off-label use of INFUSE™, MEDTRONIC recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these off-label risks while

promoting INFUSE™ to spine surgeons for off-label uses. In fact, MEDTRONIC promoted to spine surgeons and patients the use of INFUSE™ in dangerous off-label procedures, thereby demonstrating a conscious disregard for the health and safety of spinal fusion patients, such as the Plaintiff.

12. Moreover, the actual rate of incidence of serious side effects from off-label use of INFUSE™ is, in fact, much greater than MEDTRONIC disclosed to spine surgeons and patients. Regarding the off-label approaches, MEDTRONIC failed to accurately disclose the significant off-label risks that it knew or should have known.

13. Because of MEDTRONIC's wrongful conduct in actively and illegally promoting the off-label uses of INFUSE™ and because of MEDTRONIC's additional wrongful conduct in minimizing, concealing, and/or downplaying the true risks of these non-FDA approved off-label uses of MEDTRONIC's INFUSE™, thousands of spine patients, including Plaintiff, underwent surgeries without knowing the true risks inherent in the off-label use of INFUSE™.

14. These patients and their physicians relied on MEDTRONIC's false and misleading statements of material fact including statements and publications by MEDTRONIC's "opinion leaders," "thought leaders," and sales representatives. MEDTRONIC orchestrated a marketing campaign from at least 2002 to the present to persuade spine surgeons to use INFUSE™ in dangerous off-label uses in the spine. Indeed, absent MEDTRONIC's extensive off-label promotion campaign, physicians, such as the Plaintiff's spine surgeon, would never have performed these especially risky off-label procedures.

15. As a result of off-label INFUSE™ surgery using off-label procedures and/or components, Plaintiff suffered bodily injuries and damages as described herein.

PARTIES

PLAINTIFFS

16. Plaintiff TERRY MARTINEZ is an adult individual who at all times relevant hereto was residing in the State of California. On December 22, 2009, Plaintiff TERRY MARTINEZ presented at Good Samaritan Hospital, where Dr. David Yeh performed a surgical

procedure: the transfemoral lumbar interbody arthrodesis at L5-S1, the placement of crescent PEEK cage at L5-S1, the posterolateral arthrodesis at L5-S1, the non-segmental pedicle screw instrumentation at L5-S1, and the placement of allograft for fusion. On October 12,2010, Plaintiff presented at Good Samaritan Hospital, where Dr. David Yeh performed a second surgical procedure: the redoing posterior lumbar interbody fusion at L5-S1 from the right, the segmental pedicle screw instrumentation at L4, L5, and S1 bilaterally, and the placement of morselized autograft, as well as allograft for fusion. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff TERRY MARTINEZ now suffers from severe injuries and damages, including but not limited to difficulty standing, chronic pain syndrome, left leg dysesthesias, neck and shoulder pain with radiculopathy, cord compression, dysthymia, depression, headaches, incapacitating pain, suicidal thoughts, anxiety, narcotic dependence from prescribed painkillers, other emotional distress and mental anguish, and suboccipital, lumbosacral, cervical, and shoulder myofascial syndromes. December 2011 was the first time that Plaintiff TERRY MARTINEZ had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff TERRY MARTINEZ did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until the December 2011 at the earliest.

17. Plaintiff JOHNNY BALLINGER is an adult individual who at all times relevant hereto was residing in the State of Kentucky. On January 29, 2008, Plaintiff JOHNNY BALLINGER presented at Norton Hospital, where Dr. Steven Glassman performed a surgical procedure: the anterior cervical discectomy and fusion from C4-C6. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff JOHNNY BALLINGER now suffers from severe neck and back pain, including difficulty swallowing, chronic pain

syndrome, suicidal thoughts and anxiety, and narcotic dependence from prescribed painkillers. February 2013 was the first time that Plaintiff JOHNNY BALLINGER should have had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JOHNNY BALLINGER did not know and his injury could not have been known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until February 2013 at the earliest.

18. Plaintiff TIMERY UEBBING is an adult individual who at all times relevant hereto was residing in the State of Michigan. On August 13, 2007, Plaintiff TIMERY UEBBING presented at Oakwood Hospital, where Dr. Fredrick Junn performed a surgical procedure: the cord compression secondary to herniated disc at C6-7, the posterior portion of the discectomy, and the congenital fusion C5-6. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff TIMERY UEBBING now suffers from severe injuries and damages including neck pain, cervical radiculopathy, and 15-20 types cancer. July 2012 was the first time that Plaintiff TIMERY UEBBING had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff TIMERY UEBBING did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until July 2012 at the earliest.

19. Plaintiff TABATHIA GATES is an adult individual who at all times relevant hereto was residing in the State of Tennessee. On December 23, 2009, Plaintiff TABATHIA GATES presented at Skyridge Medical Center, where Dr. Rickey Hutcheson performed a surgical procedure: the anterior cervical discectomy at C7 and arthrodesis at C6-7, the anterior cervical plating using the Pioneer plating system C6 to C7 using an anterior cervical plate, the cage insertion, and the allografting using Vitoss allograft. On January 20, 2010, Plaintiff TABATHIA GATES presented at Skyridge Medical Center, where Dr. Rickey Hutcheson

performed a second surgical procedure: the decompression laminectomy at L5, the anterior discectomy of L5-S1 from the posterior side, the anterior interbody fusion L5-S1 using allograft, autograft, and infuse, the posterior lateral fusion at L5-S1, and the posterior lateral instrumentation at L5-S1. As a direct and proximate result of the use of INFUSE™ in this cervical and lumbar fusion surgery, Plaintiff TABATHIA GATES now suffers from severe injuries and damages, including neck pain, back pain, chest pain, headache, herniated bulging discs, bulging discs, and unwanted bone growth. April 2013 was the first time that Plaintiff TABATHIA GATES had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff TABATHIA GATES did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the end of April 2013 at the earliest.

20. Plaintiff SHARON WHITE is an adult individual who at all times relevant hereto was residing in the State of Florida. On February 27, 2009, Plaintiff SHARON WHITE presented at Broward Health, where Dr. Gary Gieseke performed a surgical procedure: the anterior cervical discectomy, the bilateral foraminotomy of nerve roots and dural sac with arthrodesis using PEEK cages/INFUSE, and the zephyr plating C5, C6, and C7. Plaintiff SHARON WHITE later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff SHARON WHITE now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, desiccated spinal discs, cardiovascular injuries, liver damage, unwanted bone growth, cyst formation, herniated bulging discs, bulging discs, muscloskeletal injuries, deterioration of the spine, anxiety, and narcotic dependence from prescribed painkillers. October 2012 was the first time that Plaintiff SHARON WHITE had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHARON WHITE did not know and could not have

known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until October 2012 at the earliest.

21. Plaintiff SARA MCMILLAN is an adult individual who at all times relevant hereto was residing in the State of Ohio. On April 6, 2010, Plaintiff SARA MCMILLAN presented at Mount Carmel New Albany Hospital, where Dr. Larry Todd performed a first surgical procedure: the laminectomy decompression with excision of disk protrusions at both the L3-4 and L4-5 levels, the posterior spinal fusion instrumentation with interbody allograft at the L3-4, L4-5 levels, and the infuse BMP for the posterior fusion part of the procedure at the L3-4, L4-5 levels. On June 6, 2013, Plaintiff SARA MCMILLAN presented at Mount Carmel New Albany Hospital, where Dr. Larry Todd performed a second surgical procedure: the removal of hardware with exploration of fusion mass with findings of a pseudoarthrosis from the L3 to L5 level and the repeating uninstrumented posterolateral fusion from the L3 to L5 level. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff SARA MCMILLAN now suffers from severe injuries and damages, including difficulty swallowing, chronic back pain, incapacitating pain, and narcotic dependence from prescribed painkillers. March 2013 was the first time that Plaintiff SARA MCMILLAN had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SARA MCMILLAN did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the March 2013 at the earliest.

22. Plaintiff ROSILAND SPENCER is an adult individual who at all times relevant hereto was residing in the State of Alabama. On September 20, 2007, Plaintiff ROSILAND SPENCER presented at Helen Keller Hospital, where Dr. James Jerry Adderholt performed a surgical procedure: the anterior cervical discectomy and fusion using cornerstone interbody graft

and Atlantis anterior cervical plate at C5-C7 levels. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff ROSILAND SPENCER now suffers from severe injuries and damages. June 2013 was the first time that Plaintiff ROSILAND SPENCER had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff ROSILAND SPENCER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the June 2013 at the earliest.

23. Plaintiff RONDA HOULE is an adult individual who at all times relevant hereto was residing in the State of Georgia. Plaintiff RONDA HOULE presented at the Regional Medical Center in Madisonville, KY, where Dr. James Donley performed two decompressive laminectomies – one on n December 15, 2005, and the other on February 10, 2006. Then, on October 30, 2006, Plaintiff RONDA HOULE presented at Southern Hills Medical center, where Dr. Thomas Jeff O'Brien performed a surgical procedure: the revision L4-L5 decompression with instrumented spinal fusion/TLIF. On December 19, 2007, Plaintiff RONDA HOULE presented at Texas Back Institute, where Dr. William D Bradley performed a surgical procedure: the revision decompression at right L5, the additional level decompression at L4, the additional level decompression at L6, and the intraoperative use of microscope. Plaintiff RONDA HOULE later returned home, but her pain and difficulties standing and sitting did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff RONDA HOULE now suffers from severe injuries and damages, including chronic pain syndrome, difficulties walking, difficulties standing, difficulties sitting, difficulties sleeping, and narcotic dependence from prescribed painkillers. December 2012 was the first time that Plaintiff RONDA HOULE had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff RONDA

HOULE did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the end of December 2012 at the earliest.

24. Plaintiff NINA VINCENT is an adult individual who at all times relevant hereto was residing in the State of Alabama. On January 27, 2010, Plaintiff NINA VINCENT presented at Huntsville Hospital, where Dr. Larry M. Parker performed a surgical procedure: the decompressive laminectomy with right L4 and L5 foraminotomies, the posterolateral fusion, L4-5, and the posterior instrumentation, L4-5 with spinal USA titanium hardware. On February 03, 2010, Plaintiff NINA VINCENT presented at Huntsville Hospital, where Dr. Larry M. Parker and Richard R. Randall performed a surgical procedure: the anterior retroperitoneal exposure and the anterior interbody fusion of L4-5. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff NINA VINCENT now suffers from severe injuries and damages. January 2013 was the first time that Plaintiff NINA VINCENT had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff NINA VINCENT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until January 2013 at the earliest.

25. Plaintiff MICHAEL MCMILLAN is an adult individual who at all times relevant hereto was residing in the State of Ohio. On March 9, 2010, Plaintiff MICHAEL MCMILLAN presented at Mount Carmel New Albany Hospital, where Dr. Larry Todd performed a surgical procedure: the infuse bone morphogenic protein for the posterior fusion part of the procedure at the L4-5 and L5-S1 level. After the infuse bone graft surgery, his pain and difficulties standing did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff MICHAEL MCMILLAN now suffers from severe injuries and damages including difficulty standing, chronic pain syndrome, occipital neuralgia, back pain, and neck

pain. March 2012 was the first time that Plaintiff MICHAEL MCMILLAN had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff MICHAEL MCMILLAN did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until the end of March 2012 at the earliest.

26. Plaintiff MAUREEN JACQUES is an adult individual who at all times relevant hereto was residing in the State of Connecticut. On July 13, 2006, Plaintiff MAUREEN JACQUES presented at New Britain General Hospital, where Dr. Ahmed M. Khan and Lane Spero performed a surgical procedure: the posterior cervical fusion C4-5, C5-6, and C6-7 and the use of morcellized allograft. Plaintiff MAUREEN JACQUES later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff MAUREEN JACQUES now suffers from severe injuries and damages, including chronic pain syndrome, neck pain, back pain, leg pain, and shoulder pain. October 2012 was the first time that Plaintiff MAUREEN JACQUES had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MAUREEN JACQUES did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until October 2012 at the earliest.

27. Plaintiff LORI SHOULDERS is an adult individual who at all times relevant hereto was residing in the State of Illinois. On January30, 2002, Plaintiff LORI SHOULDERS had a first posterior cervical fusion surgery at the C5-7 levels at Methodist Hospital. On October 3, 2002, Plaintiff LORI SHOULDERS presented at Deaconess Hospital, where Dr. Matthew B. Kern performed a second surgical procedure: the removal and replacement of left C6 lateral mass screw of left C5 and the lateral mass screw removal and placement of Infuse and cancellus bone left and refusion of left C6-7 facet with placement of Infuse and cansellus bone. After the second

surgery, her neck pain did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff LORI SHOULDERS now suffers from severe injuries and damages, including difficulty standing, chronic neck pain, incapacitating pain, and narcotic dependence from prescribed painkillers. June 2012 was the first time that Plaintiff LORI SHOULDERS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff LORI SHOULDERS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the June 2012 at the earliest.

28. Plaintiff LEONARD HUNTER is an adult individual who at all times relevant hereto was residing in the State of Missouri. On April 30, 2008, Plaintiff LEONARD HUNTER presented at Barnes Jewish Hospital, where Dr. Timothy R. Kuklo performed a surgical procedure: the anterior cervical diskectomy and fusion of the C3-C6, the bilateral foraminotomy at C3-C4 and C5-C6, the bilateral laminotomy at C4-C5, and the placement of an anterior cervical plate C4-C6. After his operation, he had a different type of injuries. Plaintiff LEONARD HUNTER later returned home, but his pain and difficulties breathing and swallowing did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff LEONARD HUNTER now suffers from severe injuries and damages, including difficulties swallowing and breathing, difficulties sleeping, a swollen throat, choking, neck pain, bilateral arm pain and tingling, esophageal fibrotic changes, and inflammatory changes. March 2012 was the first time that Plaintiff LEONARD HUNTER had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff LEONARD HUNTER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until the end of March 2012 at the earliest.

29. Plaintiff JIMMY WEEKS is an adult individual who at all times relevant hereto was residing in the State of Mississippi. On July 24, 2007, Plaintiff JIMMY WEEKS presented

at Greenwood Leflore Hospital, where Dr. Remi Nader performed a surgical procedure: the L5-S1 lumbar interbody fusion using the bone autograft, the L5-S1 bilateral pedicle screw fixation and Medtronic screws, and the use of infuse bone morphogenic protein for interbody arthrodesis. On September 12, 2007, Plaintiff JIMMY WEEKS presented at Greenwood Leflore Hospital, where Dr. Remi Nader performed a second surgical procedure: the L5, partical S1 and partical L4 bilateral laminectomises and decompression and the redo L5-S1 left sided foraminotomies. Plaintiff JIMMY WEEKS later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff JIMMY WEEKS now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, chest pain, lumbar radiculopathy, myofascial pain, cervical radiculopathy, anxiety, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff JIMMY WEEKS had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JIMMY WEEKS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until May 2012 at the earliest.

30. Plaintiff ISABEL BUCKHOLDT is an adult individual who at all times relevant hereto was residing in the State of Texas. On October 30, 2006, Plaintiff ISABEL BUCKHOLDT had a first surgical operation to release her back and leg pain at Southwest Texas Methodist Hospital, where Dr. Lloyd A. Youngblood made the surgery: the anterior discectomy, interbody fusion, and plating from C4 to C7. On May 24, 2007, Plaintiff ISABEL BUCKHOLDT presented at Southwest Texas Methodist Hospital, where Dr. Robert G Johnson and Lloyd A. Youngblood performed a second surgical procedure: the L4 to S1 decompression, internal fixation and fusion. Ms. Buckholdt has continued her pain management with Dr. Whiting, Dr. Sharma, and Stephanie Jones for 6 years, but her main problem is the chronic

cervical and low-back pain. As a direct and proximate result of the use of INFUSE™ in this cervical and lumbar fusion surgery, Plaintiff ISABEL BUCKHOLDT now suffers from severe injuries and damages, including difficulty standing, chronic back and neck pain, incapacitating pain, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff ISABEL BUCKHOLDT had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff ISABEL BUCKHOLDT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until the August 2012 at the earliest.

31. Plaintiff DYLAN WEST is an adult individual who at all times relevant hereto was residing in the State of Ohio. On April 07, 2008, Plaintiff DYLAN WEST presented at Cincinnati Children's Hospital Medical Center, where Dr. A. Atiq Durrani performed a surgical procedure: the T8-9 interbody fusion with cage, and the hemilaminotomy of T8 and a decompression, and the T7 to T10 posterior spinal fusion and instrumentation with auto/allograft bone grafting. Plaintiff DYLAN WEST later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this thoracic fusion surgery, Plaintiff DYLAN WEST now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, chest pain, spinal fractures, desiccated spinal discs, cyst formation, herniated bulging discs, bulging discs, muscloskeletal injuries, deterioration of the spine, anxiety, and narcotic dependence from prescribed painkillers. July 2012 was the first time that Plaintiff DYLAN WEST had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff DYLAN WEST did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until July 2012 at the earliest.

32. Plaintiff AUDRA GUERRETTAZ is an adult individual who at all times relevant hereto was residing in the State of Washington. On June 05, 2009, Plaintiff AUDRA GUERRETTAZ presented at Kaiser Permanente, where Dr. Charles Wrobel performed a surgical procedure: the anterior cervical disc excision and fusion C5-6 and C6-7. Plaintiff AUDRA GUERRETTAZ later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff AUDRA GUERRETTAZ now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, arm pain, leg pain, shoulder pain, unwanted bone growth, herniated bulging discs, bulging discs, obesity, deterioration of the spine, anxiety, and narcotic dependence from prescribed painkillers. September 2012 was the first time that Plaintiff AUDRA GUERRETTAZ had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff AUDRA GUERRETTAZ did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until September 2012 at the earliest.

33. Plaintiff HASKELL CROFT is an adult individual who at all times relevant hereto was residing in the State of Georgia. On December 15, 2008, Plaintiff HASKELL CROFT presented at Memorial Hospital, where Dr. Scott Hodges performed a surgical procedure: the transforaminal interbody cage insertion (Capstone cage with BMP) L4-5, L5-S1 and the posterior lateral interbody fusion with local bone graft L4-5, L5-S1. On March 23, 2011, Plaintiff HASKELL CROFT presented at Memorial Hospital, where Dr. Scott Hodges performed a second surgical procedure: the left L5 complete facetectomy and the hardware removal left L5 to S1. Plaintiff HASKELL CROFT later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery,

Plaintiff HASKELL CROFT now suffers from severe injuries and damages, including chronic pain syndrome, hip pain, leg pain, unwanted bone growth, anxiety, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff HASKELL CROFT had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff HASKELL CROFT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until August 2012 at the earliest.

34. Plaintiff DAWN TRUAX is an adult individual who at all times relevant hereto was residing in the State of Colorado. On February 15, 2006, Plaintiff DAWN TRUAX presented at Vail Valley Medical Center, where Dr. Donald Corenman performed a surgical procedure: the L5-S1 TLIF with local bone, BNP and cage, posterior fusion with local bone, BNP and TSRH, instrumentation. On October 02, 2012, Plaintiff DAWN TRUAX presented at St. Anthony Hospital, where Dr. John S. Nichols performed a surgical procedure: the anterior cervical discectomy and interbody fusion using bone bank bone at C4-5, C5-6 and C6-7 with anterior titanium Atlantis plating. Plaintiff DAWN TRUAX later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar and cervical fusion surgery, Plaintiff DAWN TRUAX now suffers from severe injuries and damages, including chronic pain syndrome, neck pain, back pain, unwanted bone growth, herniated bulging discs, deterioration of the spine, cervical radiculopathy, anxiety, and narcotic dependence from prescribed painkillers. August 2013 was the first time that Plaintiff DAWN TRUAX had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff DAWN TRUAX did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until August 2013 at the earliest.

35. Plaintiff SHANNON COMPTON is an adult individual who at all times relevant hereto was residing in the State of California. On June 04, 2007, Plaintiff SHANNON COMPTON presented at Sierra Vista Regional Medical Center, where Dr. Donald A. Ramberg performed a surgical procedure: the anterior cervical discectomy at C5-6, anterior cervical fusion at C5-6 using autologous bone graft Infuse and interbody grafting, and anterior cervical plating at C5-6 using atomic cervical plate. Plaintiff SHANNON COMPTON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff SHANNON COMPTON now suffers from severe injuries and damages, including chronic pain syndrome, neck pain hand pain, arm pain, carpal tunnel syndrome, thoracic outlet syndrome, wrist pain, numbness, deterioration of the spine, cervical radiculopathy, anxiety, and narcotic dependence from prescribed painkillers. April 2013 was the first time that Plaintiff SHANNON COMPTON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHANNON COMPTON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2013 at the earliest.

36. Plaintiff DEREK DAVIS is an adult individual who at all times relevant hereto was residing in the State of Ohio. On April 27, 2010, Plaintiff DEREK DAVIS presented at White Plains Hospital Center, where Dr. Jack Stern performed a surgical procedure: the microlumbar discectomy with removal of an extruded disk fragment at L4-5 on the left. On February 8, 2011, Plaintiff DEREK DAVIS presented at White Plains Hospital Center, where Dr. Seth Neubardt performed a surgical procedure: the posterior lumbar interbody fusion L4-5 and L5-S1 using interbody cage device with local autogenous bone graft and with synthetic bone graft product with bone marrow aspirate with pedicle screw instrumentation left L4-L5-S1 and

posterolateral fusion under fluoroscopic guidance with intraoperative running and evoked nerve monitoring. On December 8, 2012, Plaintiff DEREK DAVIS presented at White Plains Hospital Center, where Dr. Seth Neubardt performed a surgical procedure: the removal of hardware left side L4, L5, and S1 with exploration of fusion mass under fluoroscopic guidance. Plaintiff DEREK DAVIS later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff DEREK DAVIS now suffers from severe injuries and damages, including chronic pain syndrome, low back and buttock pain, leg pain, deterioration of the spine, bulging discs, anxiety, depression, and narcotic dependence from prescribed painkillers. December 2012 was the first time that Plaintiff DEREK DAVIS had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff DEREK DAVIS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until December 2012 at the earliest.

37. Plaintiff NORVEL DICKENS is an adult individual who at all times relevant hereto was residing in the State of Texas. On July 8, 2010, Plaintiff NORVEL DICKENS presented at Huntsville Hospital, where Dr. Cyrus Ghavam performed a surgical procedure: the anterior cervical fusion at C5-6, the insertion of a spinal USA PEEK cage at C5-6 filled with one-third of one strip of infuse, the anterior cervical hardware removal, and the anterior cervical plating at C5-6 using spinal USA plate with screws. Plaintiff NORVEL DICKENS later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff NORVEL DICKENS now suffers from severe injuries and damages, including chronic pain syndrome, neck pain, unwanted bone growth, cyst formation, hernia, obstruction of airway, anxiety, and narcotic dependence from prescribed painkillers. April 2012 was the first time that Plaintiff NORVEL DICKENS had

reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff NORVEL DICKENS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until April 2012 at the earliest.

38. Plaintiff GANA BRETT is an adult individual who at all times relevant hereto was residing in the State of Nebraska. On July 12, 2010, Plaintiff GANA BRETT presented at Nebraska Orthopaedic Hospital, where Dr. Robert Zadalis and Jonathan Fuller performed a surgical procedure: the anterior L4-S1 diskectomy and fusion via a left retroperitoneal incision. Plaintiff GANA BRETT later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff GANA BRETT now suffers from severe injuries and damages, including chronic pain syndrome, low back pain, left flank and abdominal pain, unwanted bone growth, anxiety, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff GANA BRETT had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff GANA BRETT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until August 2012 at the earliest.

39. Plaintiff JIMMY HENDRICH is an adult individual who at all times relevant hereto was residing in the State of Missouri. On January, 4, 2008, Plaintiff JIMMY HENDRICH presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the T7-T8 posterior spinal fusion with instrumentation, the augmentation of posterior spinal fusion with local bone graft, and the right T7-T8 laminotomy, foraminotomy, and discectomy. On March, 28, 2008, Plaintiff JIMMY HENDRICH presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the right C4-C5 posterior cervical fusion, the right C5-C6 foraminotomy, and the augmentation of posterior cervical fusion with bone

morphogenic protein and local bone graft. On January, 21, 2009, Plaintiff JIMMY HENDRICH presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the T3-T4 and T5-T6 laminectomy foraminotomy and diskectomy, the T3-T4 and T5-T6 anterior spinal fusion with placement of local bone graft, and the posterior spinal fusion at T3-T8 with local bone graft and BMP. Plaintiff JIMMY HENDRICH later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical and thoracic fusion surgery, Plaintiff JIMMY HENDRICH now suffers from severe injuries and damages, including chronic pain syndrome, back pain, neck pain, arm pain, shoulder pain, numbness and tingling, anxiety, and narcotic dependence from prescribed painkillers. January 2012 was the first time that Plaintiff JIMMY HENDRICH had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JIMMY HENDRICH did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until January 2012 at the earliest.

40. Plaintiff JEFFERY HINES is an adult individual who at all times relevant hereto was residing in the State of Kentucky. On January 13, 2009, Plaintiff JEFFERY HINES presented at Norton Hospital, where Dr. David P. Rouben performed a surgical procedure: the left-sided transforaminal posterior interbody fusion L3-4, L4-5, and L5-S1, the pedicle instrumentation L3, L4, L5, and S1 bilateral, the posterior spinal fusion L3-4, L4-5, and L5-S1, and the cage instrumentation L3-4, L4-5, and L5-S1. On January 23, 2009, Plaintiff JEFFERY HINES presented at Norton Hospital, where Dr. David P. Rouben performed a second surgical procedure: the reinsertion of new left S1 pedicle screw and the complex closure of deep wound, postoperative wound, and lumbosacral fusion. Plaintiff JEFFERY HINES later returned home, but his back and leg pain and weakness did not subside. As a direct and proximate result of the

use of INFUSE™ in this lumbar fusion surgery, Plaintiff JEFFERY HINES now suffers from severe injuries and damages, including chronic pain syndrome, left leg pain, low back pain, left leg numbness, muscle spasms, right foot symptoms, left leg symptoms and narcotic dependence from prescribed painkillers. January 2013 was the first time that Plaintiff JEFFERY HINES had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff JEFFERY HINES did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until January 2013 at the earliest.

41. Plaintiff BRENDA LANDIS is an adult individual who at all times relevant hereto was residing in the State of Pennsylvania. On April 18, 2008, Plaintiff BRENDA LANDIS presented at Geisinger Medical Center, where Dr. Darren Jacobs performed a surgical procedure: the L4-S1 interbody fusion with PEEK structural cage using Capstone Medtronic graft filled with Infuse rhBMP (bone morghogenic protein) and morcellized autograft and the bilateral lateral allograft fusion using Infuse rhBMP (recombinant human morphogenic protein). On January 8, 2010, Plaintiff presented at Geisinger Medical Center, where Dr. Darren Jacobs performed a second surgical procedure: the thoracic laminotomy and placement of dorsal column stimulator epidural electrodes and the programming of dorsal column stimulator device. Plaintiff BRENDA LANDIS later returned home, but her back and leg pain did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff BRENDA LANDIS now suffers from severe injuries and damages, including chronic pain syndrome, leg pain, back pain, unwanted bone growth, obesity, cyst formation, bulging discs, and narcotic dependence from prescribed painkillers. April 2013 was the first time that Plaintiff BRENDA LANDIS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff BRENDA

LANDIS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2013 at the earliest.

42. Plaintiff PATRICK MCCOY is an adult individual who at all times relevant hereto was residing in the State of Texas. On September 10, 2007, Plaintiff PATRICK MCCOY presented at Pine Creek Surgery Center, where Dr. John Milani performed a surgical procedure: the laminectomy and discectomy at L3 and L4, posterior lumbar interbody fusion at L3 and L4, the placement of hardware from L3 to L5 bilaterally, and the utilization of bone morphogenic protein. Plaintiff PATRICK MCCOY later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff PATRICK MCCOY now suffers from severe injuries and damages including severe back pain. July 2012 was the first time that Plaintiff PATRICK MCCOY had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff PATRICK MCCOY did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until July 2012 at the earliest.

43. Plaintiff JOHN MANCUSO is an adult individual who at all times relevant hereto was residing in the State of New York. On April 4, 2008, Plaintiff JOHN MANCUSO presented at Beth Israel Medical Center, where Dr. Paul Kuflik performed a surgical procedure: the posterior spine fusion at L4-L5 and L5-S1 segment fixation using CD-LEGACY and the injection of intrathecal duramorph; the osteotomy L4-L5 bone morphogenic protein and local bone graft. Plaintiff JOHN MANCUSO later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff JOHN MANCUSO now suffers from severe injuries and damages including severe back pain. July 2012 was the first time that Plaintiff JOHN MANCUSO had reason to suspect that

INFUSE™ caused his symptoms. Thus, Plaintiff JOHN MANCUSO did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until July 2012 at the earliest.

44. Plaintiff MARSHA MORRIS is an adult individual who at all times relevant hereto was residing in the State of Georgia. On July 23, 2009, Plaintiff MARSHA MORRIS presented at Gwinnet Medical Center, where Dr. Douglas Kasow performed a surgical procedure: the anterior lumbar decompression at L5-S1, the anterior lumbar arthrodesis at L1-S1, the insertion of spinal cage prosthesis at L5-S1, the anterior segmental instrumentation at L5-S1, and the utilization of fluoroscopy for localization and instrumentation. Plaintiff MARSHA MORRIS later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff MARSHA MORRIS now suffers from severe injuries and damages. April 2012 was the first time that Plaintiff MARSHA MORRIS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MARSHA MORRIS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2012 at the earliest.

45. Plaintiff ANTHONY MORMIL is an adult individual who at all times relevant hereto was residing in the State of New Jersey. On March 2, 2004, Plaintiff ANTHONY MORMIL presented at West Jersey Hospital, where Dr. Kamaldeep Momi performed a surgical procedure: the bilateral C3 to C7 keyhole foraminotomies with revision foraminotomy at C3-C4 bilaterally, the C6-C7 laminectomy, the C4-C7 lateral mass screw fixation, and the C4-C7 fusion utilizing crushed allograft. Plaintiff ANTHONY MORMIL later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff ANTHONY MORMIL now suffers from severe injuries and

damages including neck pain, back pain, shoulder pain, male infertility, neck fractures, infection in the neck and bank, bulging discs, obstruction of airway, deterioration of the spine, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff ANTHONY MORMIL had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff ANTHONY MORMIL did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until May 2012 at the earliest.

46. Plaintiff PIO EMILIA is an adult individual who at all times relevant hereto was residing in the State of Florida. On July 24, 2006, Plaintiff PIO EMILIA presented at Coral Gables Hospital, where Dr. Allan Jorge performed a surgical procedure: the L3- S1 pedicle fusion and decompression, the L4-5 discectomy and interbody fusion, the far lateral arthrodesis at L3-S1, and the bilateral laminectomies from L3-5. Plaintiff PIO EMILIA later returned home, but her pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff PIO EMILIA now suffers from severe injuries and damages including chronic pain syndrome, muscle spasticity, back pain, neck pain, hip pain, groin pain, burning and stabbing pain, tenderness and numbness in the leg, unwanted bone growth, anxiety, depression, and narcotic dependence from prescribed painkillers. February 2012 was the first time that Plaintiff PIO EMILIA had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff PIO EMILIA did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2012 at the earliest.

47. Plaintiff NANCY SCHREIBER is an adult individual who at all times relevant hereto was residing in the State of Georgia. On March 21, 2005, Plaintiff NANCY SCHREIBER

presented at Emory University Hospital, where Dr. John Heller performed a surgical procedure: the anterior interbody fusion at C4-C5 and C5-C6, the anterior cervical discectomies at C4-C5 and C5-C6, and the anterior spinal instrumentation with Atlantic plate at C4 to C6. Plaintiff NANCY SCHREIBER later returned home, but her pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff NANCY SCHREIBER now suffers from severe injuries and damages including chronic pain syndrome, back pain, anxiety, depression, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff NANCY SCHREIBER had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff NANCY SCHREIBER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until August 2012 at the earliest.

48. Plaintiff WILLIE STANBERRY JR. is an adult individual who at all times relevant hereto was residing in the State of Pennsylvania. On October 29, 2009, Plaintiff WILLIE STANBERRY JR. presented at Cleveland Clinic, where Dr. Teresa Ruch performed a surgical procedure: the laminectomy and foraminotomies bilaterally using BMP to treat L4-5 stenosis and L5-S1 spondylolisthesis and spondylolysis with degenerative disk disease. Plaintiff WILLIE STANBERRY JR. later returned home, but his pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff WILLIE STANBERRY JR. now suffers from severe injuries and damages including chronic pain syndrome, neck pain, back pain, anxiety, depression, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff WILLIE STANBERRY JR. had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff WILLIE

STANBERRY JR. did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until August 2012 at the earliest.

49. Plaintiff DOUGLAS PRESTIDGE is an adult individual who at all times relevant hereto was residing in the State of Arizona. On August 12, 2004, Plaintiff DOUGLAS PRESTIDGE presented at Southern Arizona VA Health Care, where Dr. Karsten Fryburg performed a surgical procedure: the anterior cervical discectomy at C5-C6 and C6-C7 with harvesting of iliac crest bone graft and the arthrodesis at C5-6 and C6-7 with plating. Plaintiff DOUGLAS PRESTIDGE later returned home, but his pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff DOUGLAS PRESTIDGE now suffers from severe injuries and damages including chronic pain syndrome, neck pain, back pain, desiccated spinal discs, cyst formation, bulging discs, unwanted bone growth, obstruction of airway, deterioration of the spine, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff DOUGLAS PRESTIDGE had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff DOUGLAS PRESTIDGE did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until May 2012 at the earliest.

50. Plaintiff MARYANNE WAGNER is an adult individual who at all times relevant hereto was residing in the State of Illinois. On December 8, 2009, Plaintiff MARYANNE WAGNER presented at Centennial Medical Center, where Dr. Jacob Schwarz performed a surgical procedure: the C3 to C7 anterior cervical discectomy and fusion. On February 23, 2010, Plaintiff MARYANNE WAGNER presented at Centennial Medical Center, where Dr. Jacob Schwarz performed a surgical procedure: the one-level L4 to S1 transforaminal lumbar interbody fusion. Plaintiff MARYANNE WAGNER later returned home, but her pain and difficulties did

not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar and cervical fusion surgery, Plaintiff MARYANNE WAGNER now suffers from severe injuries and damages, including foraminal stenosis, facet hypertrophy, difficulty walking, chronic pain syndrome, lumbar spondylolysis, cervical spodylolysis, neck pain, bilateral arm pain, low back pain, bilateral leg pain, numbness, tingling, lumber radiculopathy, and spinal fractures. April 2012 was the first time that Plaintiff MARYANNE WAGNER had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MARYANNE WAGNER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2012 at the earliest.

51. Plaintiff BYOTHA THOMAS is an adult individual who at all times relevant hereto was residing in the State of Ohio. On July 29, 2004, Plaintiff BYOTHA THOMAS presented at Florida Hospital, where Dr. Richard Smith performed a surgical procedure: the posterior lumbar interbody fusion at L5-S1, the insertion of cages and vertebral body defects at L5-S1, the insertion of segmental spinal instrumentation and lumbar spine, the bilateral posterolateral fusion at L5-S1. Plaintiff BYOTHA THOMAS later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff BYOTHA THOMAS now suffers from severe injuries and damages including chronic pain syndrome, back pain, spinal fractures, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff BYOTHA THOMAS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff BYOTHA THOMAS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until May 2012 at the earliest.

52. Plaintiff PATRICIA SHEPARD is an adult individual who at all times relevant hereto was residing in the State of North Carolina. On May 23, 2007, Plaintiff PATRICIA SHEPARD presented at New Hanover Regional Medical Center, where Dr. George Huffmon performed a surgical procedure: the C3-C7 anterior cervical disckectomy and arthrodesis, the verte-stack interbody spacers, the ant-cer plate C3-C7, and the left iliac crest bone marrow aspirate, grafton local autograft, and microscope with fluoroscopy. On June 4, 2008, Plaintiff PATRICIA SHEPARD presented at New Hanover Regional Medical Center, where Dr. George Huffmon performed a surgical procedure: the C3, C4, C5, C6, and C7 posterior cervical fusion. On April 28, 2011, Plaintiff PATRICIA SHEPARD presented at New Hanover Regional Medical Center, where Dr. Jon Miller performed a surgical procedure: the decompression L4-5 and L5-S1, the transforaminal lumbar interbody fusion L4-L5 and L5-S1, the placement of interbody cages, the posterior instrumentation L4-5 and L5-S1, and the grafting with cancellous allograft supplemented with bone morphogenic protein. Plaintiff PATRICIA SHEPARD later returned home, but her pain and difficulties did not subside As a direct and proximate result of the use of INFUSE™ in this cervical and lumbar fusion surgery, Plaintiff PATRICIA SHEPARD now suffers from severe injuries and damages including chronic pain syndrome, back pain, neck pain, anxiety, and narcotic dependence from prescribed painkillers. December 2012 was the first time that Plaintiff PATRICIA SHEPARD had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff PATRICIA SHEPARD did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until December 2012 at the earliest.

53. Plaintiff ROSEMARY PENTON is an adult individual who at all times relevant hereto was residing in the State of Alabama. On September 18, 2008, Plaintiff ROSEMARY

PENTON presented at North Florida Surgery Center, where Dr. Robert Sackheim performed a surgical procedure: the lumbar discograghy at L3-L4, L4-L5, and L5-S1. On June 10, 2009, Plaintiff ROSEMARY PENTON presented at Sacred Heart Hospital, where Dr. Charles Wolff performed a surgical procedure: the retroperitoneal approach for L5-S1 anterior lumbar interbody fusion, the bilateral discectomy at L5-S1, the placement of intervertebral body device, synthes PEEK cage with bone morphogenic protein in the interspace of L5-S1, the anterior column arthrodesis at L5-S1, and the anterior lumbar plating, placement of anterior lumbar locking plate at L5-S1. Plaintiff ROSEMARY PENTON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff ROSEMARY PENTON now suffers from severe injuries and damages including chronic pain syndrome, back pain, herniated bulging discs, allergic reaction, bulging discs, musuloskeletal injury, and narcotic dependence from prescribed painkillers. January 2013 was the first time that Plaintiff ROSEMARY PENTON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff ROSEMARY PENTON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until January 2013 at the earliest.

54. Plaintiff RICHARD PLUMMER is an adult individual who at all times relevant hereto was residing in the State of California. On May 3, 2010, Plaintiff RICHARD PLUMMER presented at Presbyterian Intercommunity Hospital, where Dr. Christopher Aho performed a surgical procedure: the C5-6 radical cervical discectomy, the C5-6 application of biomechanical intervertebral device, the morcellized allograft and autograft for spine surgery. On August 6, 2010, Plaintiff RICHARD PULMMER presented at Presbyterian Intercommunity Hospital, where Dr. Christopher Aho performed a surgical procedure: the C3-7 posterolateral arthrodesis

and fusion, the C3-7 laminectomy with bilateral foraminotomies, and the morcellized allograft and autograft for spine surgery. Plaintiff RICHARD PLUMMER later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff RICHARD PLUMMER now suffers from severe injuries and damages including chronic pain syndrome, back pain, shoulder pain, infection in the neck, deterioration, and narcotic dependence from prescribed painkillers. March 2012 was the first time that Plaintiff RICHARD PLUMMER had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff RICHARD PLUMMER did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until March 2012 at the earliest.

55. Plaintiff NICHOLAS SCHULTZ is an adult individual who at all times relevant hereto was residing in the State of Wisconsin. On July 15, 2003, Plaintiff NICHOLAS SCHULTZ presented at Columbia Hospital, where Dr. James Stoll performed a surgical procedure: the anterior L4-5 and vertebral resection, the anterior L4-5 and L5-S1 interbody fusion and anterior LT cages(4), and the posterior L4 to S1 fusion with posterior L4 to S1 internal fixation. Plaintiff NICHOLAS SCHULTZ later returned home, but his pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff NICHOLAS SCHULTZ now suffers from severe injuries and damages including chronic pain syndrome, back pain, leg pain, anxiety, and narcotic dependence from prescribed painkillers. January 2012 was the first time that Plaintiff NICHOLAS SCHULTZ had reason to suspect that INFUSE™ caused his symptoms. Thus, Plaintiff NICHOLAS SCHULTZ did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused his injury until January 2012 at the earliest.

56. Plaintiff MARY TIMMONS is an adult individual who at all times relevant hereto was residing in the State of California. On July 9, 2004, Plaintiff MARY TIMMONS presented at Santa Barbara Cottage Hospital, where Dr. E. Scott Conner performed a surgical procedure: the anterior cervical discectomy and fusion with partial microsurgical vertebreotomy at C5-C6 and C6-C7 utilizing segmental fixation. On July 16, 2004, Plaintiff MARY TIMMONS presented at Santa Barbara Cottage Hospital, where Dr. E. Scott Conner performed a surgical procedure: the re-exploration of anterior cervical wound, evacuation of prevertebral hematoma, placement of Jackson-Pratt drain. On February 2, 2005, Plaintiff MARY TIMMONS presented at Santa Barbara Cottage Hospital, where Dr. E. Scott Conner performed a surgical procedure: the exploration of cervical spinal fusion with removal of hardware. Plaintiff MARY TIMMONS later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff MARY TIMMONS now suffers from severe injuries and damages including chronic pain syndrome, neck pain, herniated bulging discs, allergic reaction, bulging discs, obstruction of airway, anxiety, and narcotic dependence from prescribed painkillers. February 2012 was the first time that Plaintiff MARY TIMMONS had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MARY TIMMONS did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2012 at the earliest.

57. Plaintiff MELODIE WARD is an adult individual who at all times relevant hereto was residing in the State of Wisconsin. On May 27, 2009, Plaintiff MELODIE WARD presented at ST Mary's Hospital, where Dr. Alan Lozier performed a surgical procedure: the C4-5 anterior cervical discectomy and arthrodesis with structural allograft and anterior instrumentation using the operating microscope. Plaintiff MELODIE WARD later returned home, but her pain and

difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff MELODIE WARD now suffers from severe injuries and damages including chronic pain syndrome, neck pain, suboccipital headachés, and narcotic dependence from prescribed painkillers. August 2012 was the first time that Plaintiff MELODIE WARD had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff MELODIE WARD did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until August 2012 at the earliest.

58. Plaintiff CYNTHIA GIBSON is an adult individual who at all times relevant hereto was residing in the State of Tennessee. On June 12, 2002, Plaintiff CYNTHIA GIBSON presented at Jackson Madison County general Hospital, where Dr. Glenn Barnett performed a surgical procedure: the anterior cervical discectomy and allograft fusion of C5-6 with plating of C5 to C67. On January 8, 2003, Plaintiff CYNTHIA GIBSON presented at Jackson Madison County general Hospital, where Dr. J. Michael Glover performed a surgical procedure: the posterior cervical fusion with C5 to C6 and the removal of anterior cervical plate. Plaintiff CYNTHIA GIBSON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff CYNTHIA GIBSON now suffers from severe injuries and damages including chronic pain syndrome, neck pain, herniated bulging discs, bulging discs, obstruction of airway, and narcotic dependence from prescribed painkillers. March 2013 was the first time that Plaintiff CYNTHIA GIBSON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff CYNTHIA GIBSON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until March 2013 at the earliest.

59. Plaintiff SHEILA GOODMAN-GILBERT is an adult individual who at all times relevant hereto was residing in the State of Oklahoma. On July 16, 2009, Plaintiff SHEILA GOODMAN-GILBERT presented at Hillcrest Medical Center, where Dr. John Main performed a surgical procedure: the C4-C5, C5-C6, C6-C7 anterior cervical discectomy and fusion with placement of stryker PEEK interbody cage at C4-C7, placement of stryker reflex hybrid plate, genex with morcellized autograft for fusion material. Plaintiff SHEILA GOODMAN-GILBERT later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff SHEILA GOODMAN-GILBERT now suffers from severe injuries and damages. September 2012 was the first time that Plaintiff SHEILA GOODMAN-GILBERT had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHEILA GOODMAN-GILBERT did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until September 2012 at the earliest.

60. Plaintiff KRISTAL REED is an adult individual who at all times relevant hereto was residing in the State of Alabama. On May 16, 2006, Plaintiff KRISTAL REED presented at Brookwood Medical Center, where Dr. Charlie Talbert performed a surgical procedure: the lumbar fusion at L5-S1, the bilateral lateral transverse process fusion with pedicle screws at L5. and S1. On April 9, 2009, Plaintiff KRISTAL REED presented at ST. Vincent's Hospital, where Dr. E. Carter Morris performed a surgical procedure: the removal of lumbar pedicle screws and hardware. Plaintiff KRISTAL REED later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff KRISTAL REED now suffers from severe injuries and damages including chronic pain syndrome, back pain, leg pain, lumbar postlaminectomy syndrome, lumbar degenerative disc

disease, lumbar radiculopathy, sacroiliac pain, and narcotic dependence from prescribed painkillers. April 2013 was the first time that Plaintiff KRISTAL REED had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff KRISTAL REED did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until April 2013 at the earliest.

61. Plaintiff PENNY ROMERO is an adult individual who at all times relevant hereto was residing in the State of California. On January 29, 2008, Plaintiff PENNY ROMERO presented at Citrus Valley Medical Center, where Dr. Scott Lederhaus performed a surgical procedure: the anterior C6-7 diskectomy with plating using the zimmer plate screws and allograft bone fusion with microscopic dissection and intraoperative fluoroscopy. On December 1, 2008, Plaintiff PENNY ROMERO presented at St. Bernardine Medical Center, where Dr. Darren Bergey performed a surgical procedure: the L4-5, L5-S1 anterior lumbar discectomy and fusion using active-fuse and end-fuse, the placement of intervertebral cage at L4-5, L5-S1 using a zuma feet cage, and the anterior instrumentation at L4-5, L5-S1 using a zuma instrument, anterior plate and screws. On December 4, 2008, Plaintiff PENNY ROMERO presented at St. Bernardine Medical Center, where Dr. Darren Bergey performed a surgical procedure: the L3, L4, L5 laminectomy, the L2 and S1 bilateral laminotomy for decompression of the L4, L5, S1 nerve roots, and the fusion L4 through S1 using autograft an actifuse. Plaintiff PENNY ROMERO later returned home, but her pain and difficulties did not subside.As a direct and proximate result of the use of INFUSE™ in this lumbar and cervical fusion surgery, Plaintiff PENNY ROMERO now suffers from severe injuries and damages including chronic pain syndrome, arm pain, numbness, tingling, and narcotic dependence from prescribed painkillers. May 2012 was the first time that Plaintiff PENNY ROMERO had reason to suspect that INFUSE™ caused her

symptoms. Thus, Plaintiff PENNY ROMERO did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until May 2012 at the earliest.

62. Plaintiff SHIRLEY HANEY is an adult individual who at all times relevant hereto was residing in the State of Texas. On May 24, 1999, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center, where Dr. Robert Viere performed a surgical procedure: the anterior, complete disc excision, L4-5 and L5-S1 with partial endplate excision, the anterior lumbar interbody fusion at L4-5 and L5-S1, the redo TSRH segmental instrumentation with intrasacral fixation from T12 to S1, the redo posterior lateral fusion at T12, L1, L1-2, L4-5, and L5-S1, the removal of previous segmental instrumentation form T12 to S1, and the iliac crest bone graft. On October 15, 1999, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center , where Dr. Robert Viere performed a surgical procedure: the redo laminectomy and foraminotomy at left side of L4-L5 and L5-S1. On December 6, 2005, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center, where Dr. Robert Viere performed a surgical procedure: the revision decompression L5-S1, interbody fusion, and exploration fusion. On October, 13, 2010, Plaintiff SHIRLEY HANEY presented at Baylor University Medical Center, where Dr. Robert Viere performed a surgical procedure. Plaintiff SHIRLEY HANEY later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this lumbar fusion surgery, Plaintiff SHIRLEY HANEY now suffers from severe injuries and damages. October 2012 was the first time that Plaintiff SHIRLEY HANEY had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff SHIRLEY HANEY did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until October 2012 at the earliest.

63. Plaintiff KAREN SAPPINGTON is an adult individual who at all times relevant hereto was residing in the State of Illinois. On October 31, 2008, Plaintiff KAREN SAPPINGTON presented at Barnes Jewish Hospital, where Dr. Timothy Kuklo performed a surgical procedure: the C5-C6 and C6-C7 anterior cervical discectomy, the placement of interbody spacer C5-6 and C6-7 with anterior cervical fusion, the augmentation of anterior cervical fusion C5-6 and C6-7 with recombinant bone morphogenetic protein. Plaintiff KAREN SAPPINGTON later returned home, but her pain and difficulties did not subside. As a direct and proximate result of the use of INFUSE™ in this cervical fusion surgery, Plaintiff KAREN SAPPINGTON now suffers from severe injuries and damages including chronic pain syndrome, neck pain, bulging discs, and narcotic dependence from prescribed painkillers. February 2012 was the first time that Plaintiff KAREN SAPPINGTON had reason to suspect that INFUSE™ caused her symptoms. Thus, Plaintiff KAREN SAPPINGTON did not know and could not have known by exercising reasonable diligence that the off-label use of INFUSE™ caused her injury until February 2012 at the earliest.

DEFENDANTS

64. Defendant MEDTRONIC, INC. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Defendant MEDTRONIC, INC. is engaged in business in the State of California.

65. Defendant MEDTRONIC SOFAMOR DANEK USA, INC. ("MEDTRONIC SD") is a Tennessee corporation, with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132. Defendant MEDTRONIC, SOFAMOR DANEK USA, INC. is engaged in business in the state of California.

66. Defendant MEDTRONIC VERTELINK is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of California, with its principal

place of business in Minneapolis, Minnesota. Defendant MEDTRONIC VERTELINK, INC. is engaged in business in the State of California.

67. Defendants MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., and MEDTRONIC VERTELINK, INC., collectively known as "Medtronic" are now, and at all times mentioned in this Complaint were, in the business of designing, manufacturing, constructing, assembling, inspecting and selling various types of medical drugs and devices, including spinal surgery drugs and devices, and specifically the Infuse Bone Graft and LT-Cage, collectively known as "Infuse."

68. Defendant WYETH INC. is and at all times herein mentioned was, a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Trenton, New Jersey. Defendant WYETH INC. is engaged in business in the State of California.

69. Defendant WYETH PHARMACEUTICALS, INC. is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of Pennsylvania, with its principal place of business in Harrisburg, Pennsylvania. Defendant WYETH PHARMACEUTICALS, INC. is engaged in business in the State of California.

70. Defendant PFIZER, INC. is, and all times herein mentioned was, a corporation organized and existing under the laws of the State of New York, and maintains offices and does business in the State of California. Defendant maintains distribution centers in California, that are responsible for processing customer orders for Medtronic's rhBMP-2 drug component of the Infuse Bone Graft.

71. Defendants WYETH INC. and WYETH PHARMACEUTICALS, INC. are wholly-owned subsidiaries of PFIZER, INC., collectively known as "Wyeth" are now, and at all times mentioned in this Complaint, were, in the business of designing, manufacturing, constructing, assembling, inspecting, and selling various types of medical drugs and devices, specifically Medtronic's rhBMP-2 drug component of the Infuse Bone Graft.

51. Defendant DR. GARY K. MICHELSON is, and at all times herein mentioned was a resident

of the county of Los Angeles in the state of California. Dr. Michelson was partly responsible for inventing, designing, promoting, and marketing Medtronic's LT-Cage component of Infuse.

72. MARAL AMIRI, is a resident of the State of California, and at all times pertinent was the Area Sales Manager of Neurologic Technologies at Medtronic in Los Angeles California, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, by creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products.

73. ALEX BOLANOS is a resident of the State of California, and all times pertinent was District Sales Manager at Medtronic Spine & Biologics in Los Angeles, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, and creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products, and managing a team of spine consultants to promote the off-label use of Infuse Bone Graft.

74. KEVIN BRADLEY is a resident of the State of California, and all times pertinent was Senior District Sales Manager at Medtronic Spine & Biologics in Los Angeles, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, and creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products, and managing a team of spine consultants to promote the off-label use of Infuse Bone Graft.

75. DEBBIE PAGACH is a resident of the State of California, and all times pertinent was District Sales Manager at Medtronic Spine & Biologics in Los Angeles, whose duties included increasing market share in California by promoting and marketing Infuse Bone Graft products, and creating new referral channels and providing operating room technical support to orthopedic surgeons and neurosurgeons who use such products, and assisting hospitals throughout the Greater Los Angeles area to insure the availability of Infuse Bone Graft to individual health care providers who practice at these hospitals, and to in other ways promote the off-label use of Infuse Bone Graft.

76. Defendants Amiri, Bolanos, Bradley and Pagach, ("Defendant Medtronic Managers" or "all Defendants"), were and are in Medtronic upper management, and at all times pertinent, aware of, and did actively promote Infuse Bone Graft to various healthcare providers in the State of California, and other states, including those healthcare providers who were involved in the Plaintiffs' surgeries.

77. The true names and capacities, whether individual, corporate, associate, or otherwise, of the defendants named herein, under the fictitious names of DOES 1 through 100, inclusive, are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. Plaintiffs will ask leave of Court to amend this Complaint and insert the true names and capacities of said defendants when the same have been ascertained. Plaintiffs are informed and believe and based thereon allege that each of the defendants designated herein as "Doe" is legally responsible in some manner for the events and happenings herein alleged, and that Plaintiffs' damages were proximately caused by such defendants.

78. At all times herein mentioned, defendants, each of them, and their aggregates, corporates, associates, and partners, and each of them, were the agent, servant, employee, assignee, permissive user, successor in interest or joint venture of each other, and were acting within the time, purpose or scope of such agency or employment or permission; and all acts or omissions alleged herein of each such defendant were authorized, adopted, approved, or ratified by each of the other defendants.

79. This court has personal jurisdiction over Defendants because at all relevant times they engaged in substantial business activities in the State of California, or in the alternative, were domiciled in the State of California. At all relevant times, Defendants Medtronic, Pfizer, and Wyeth transacted, solicited, and conducted business in California through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in California. Furthermore, Dr. Michelson is a resident of the county of Los Angeles, in the State of California. The Medtronic Managers are also residents of the State of California.

1) **ALLEGATIONS**

a) **Generally.**

80. At all relevant times, INFUSE™ was researched, developed, manufactured, marketed, promoted, advertised, sold and distributed by the MEDTRONIC Defendants.

81. Plaintiffs suffered grievous personal injuries as a direct and proximate result of Defendants' misconduct.

82. In off-label lumbar or cervical spine surgeries, INFUSE™ often leads to serious complications including, but not limited to, chronic permanent radiculitis and other nerve injuries, uncontrolled bone growth, osteolysis, and poorer overall outcomes.

b) **MEDTRONIC's Representations.**

83. At all relevant times, the MEDTRONIC Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed INFUSE™ as a safe and effective device to be used for spinal fusion surgery. MEDTRONIC negligently, recklessly, and/or intentionally promoted INFUSE™ for off-label use to physicians and spine patients, including the Plaintiffs and Plaintiffs' physicians, and downplayed to physicians and spine patients its dangerous effects, including but not limited to the downplaying of the dangerous effects of INFUSE™ in off-label spine surgeries such as that performed on the Plaintiffs.

84. At all relevant times, the MEDTRONIC Defendants misrepresented the safety of INFUSE™ to physicians and patients, and recklessly, willfully, and/or intentionally failed to alert physicians and patients of the increased significant danger to patients resulting from the off-label uses of INFUSE™.

c) **MEDTRONIC's Knowledge.**

85. MEDTRONIC and its agents knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to spine surgeons regarding INFUSE™ and including MEDTRONIC's surreptitious campaign to promote the product for off-label uses (i.e. uses that had never been evaluated or approved by the FDA). The ongoing scheme described

herein could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of personnel at the highest level of MEDTRONIC, including its corporate officers.

86. At all relevant times, MEDTRONIC knew, and/or had reason to know, that INFUSE™ was not safe for off-label uses in the spine because the device had never been approved for use in the spine, other than solely in anterior approach lumbar fusion surgeries with a LT-Cage™; and its safety and efficacy for use without a LT-Cage™ was known by MEDTRONIC to be unsafe and ineffective.

87. At all relevant times, MEDTRONIC knew, and/or had reason to know that INFUSE™ was not safe for off-label use because it had not been approved for off-label use; and its safety and efficacy for off-label use was either unknown, or was known by MEDTRONIC to be unsafe and ineffective.

88. MEDTRONIC's acts to promote off-label use of INFUSE™, their knowledge of, but failure to disclose, the growing adverse events associated with the product, MEDTRONIC's continued payments to certain spine surgeon "Opinion Leaders" to promote off-label uses, repeat FDA regulatory action against MEDTRONIC, two whistleblower lawsuits against MEDTRONIC, a Department of Justice ("DOJ") settlement and resulting Corporate Integrity Agreement, and a United States Senate Finance Committee investigation culminating in a scathing report on MEDTRONIC's improper promotional activities on this product demonstrate a conscious and reckless disregard for the health and safety of spinal patients, including Plaintiff.

89. At all relevant times, the MEDTRONIC Defendants knew, and/or had reason to know, that their representations and suggestions to physicians that INFUSE™ was safe and effective for off-label use were materially false and misleading and that physicians and patients would rely on such representations.

90. MEDTRONIC knew and/or had reason to know of the likelihood of serious injuries caused by the off-label use of INFUSE™ in the spine, but they concealed this information and did not warn Plaintiffs or Plaintiffs' physicians, preventing Plaintiffs and

Plaintiffs' physicians from making informed choices in selecting other treatments or therapies prior to Plaintiffs' implantation surgery and preventing Plaintiffs and their physicians from timely discovering Plaintiffs' injuries.

91. The prevailing best scientific and medical knowledge, as discussed *supra*, demonstrated prior to the date of Plaintiffs' injury that off-label INFUSE™ was likely to cause the Plaintiffs' injuries as stated herein. This prevailing scientific and medical knowledge was known or knowable by MEDTRONIC for at least a year or more prior to Plaintiffs' off-label INFUSE™ surgery.

d) MEDTRONIC's Off-Label Promotion.

92. MEDTRONIC had knowledge and information reflecting the true risks and dangers to spine patients of off-label use of INFUSE™, the extent of the off-label use, and their reckless promotion of the off-label uses. Despite this knowledge, MEDTRONIC knowingly and recklessly conducted an egregious off-label promotion campaign to the detriment of the spine patients, including the Plaintiffs.

93. MEDTRONIC and its agents encouraged the off-label promotion of INFUSE™ described throughout this Complaint, notwithstanding their knowledge of the serious adverse events that patients could, and did, suffer, which have often resulted in the need for additional surgery, emergency intervention, and, in at least one case, the death of a patient.

94. The MEDTRONIC Defendants improperly promoted and marketed INFUSE™ to Plaintiffs' implanting surgeon for off-label use in the spine, and this improper promotion and marketing improperly influenced Plaintiffs' spine surgeon's decision to implant INFUSE™ in Plaintiffs' spine using an off-label approach.

95. The MEDTRONIC Defendants, as herein described, directly and indirectly promoted, trained, and encouraged Plaintiffs' surgeon to perform Plaintiffs' spinal fusion procedure utilizing INFUSE™ in a dangerous off-label manner.

96. The MEDTRONIC Defendants recklessly and/or fraudulently promoted and marketed INFUSE™ to Plaintiffs and Plaintiffs' physicians for off-label use in the spine.

e) **Failure to Warn.**

97. At all relevant times, the MEDTRONIC Defendants misrepresented the safety of INFUSE™ to physicians and spine patients, including to Plaintiffs and Plaintiffs' physicians, and recklessly, willfully, or intentionally failed to inform Plaintiffs or Plaintiffs' physicians of the significant dangers to patients resulting from the off-label use of INFUSE™.

98. Any warnings MEDTRONIC may have issued concerning the dangers of off-label uses of INFUSE™ or regarding the specific risks of those uses were insufficient in light of MEDTRONIC's contradictory prior, contemporaneous and continuing illegal promotional efforts and promotion of INFUSE™ for non-FDA-approved off-label uses in the spine and contemporaneous efforts to hide or downplay the true risks and dangers of the off-label uses of INFUSE™.

e) **Causation.**

99. Plaintiffs would not have consented to be treated with the off-label use of INFUSE™ had she known of or been informed by MEDTRONIC or by their spine surgeon of the true risks of the off-label use of INFUSE™.

100. Plaintiffs and Plaintiffs' spine surgeons relied on the MEDTRONIC Defendants' misrepresentations regarding the safety and efficacy of INFUSE™ in Plaintiffs' spine surgery. Plaintiffs and Plaintiffs' spine surgeon did not know of the specific risks, and/or were misled by the MEDTRONIC Defendants, who knew or should have known of the true risks but consciously chose not to inform Plaintiffs or their spine surgeon of those risks and to actively misrepresent those risks to the Plaintiffs and Plaintiffs' physician.

101. The MEDTRONIC Defendants' off-label promotion and marketing caused Plaintiffs' spine surgeons to decide to implant INFUSE™ in Plaintiffs' spine using an off-label approach.

102. Plaintiffs' spine surgeon received and relied on the MEDTRONIC Defendants' improper promotion of the off-label uses, and MEDTRONIC'S inadequate warnings which hid or downplayed the risks of off-label use of INFUSE™. Plaintiffs' spine surgeon would not have

done the procedure using off-label INFUSE™ (or using INFUSE™ at all) in the absence of MEDTRONIC's false and misleading promotion of the off-label uses.

f) Alter Ego.

103. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiffs.

104. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified those actions.

105. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between certain Defendants and other certain Defendants, such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

106. At all times herein mentioned, the MEDTRONIC Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiffs and Plaintiffs' physicians. As such, each of the MEDTRONIC Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

107. The harm which has been caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of the Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or which combination of the Defendants caused Plaintiffs' injuries.

108. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiffs.

2) The INFUSE™ Device and Spinal Fusion Surgery Generally.

109. MEDTRONIC designed and marketed INFUSE™ for lumbar spine fusion surgery, a surgical technique in which one or more of the vertebrae of the spine are united together ("fused") so that motion no longer occurs between them.

110. Spinal fusion is used to treat a number of conditions, including treatment of a fractured vertebra, spinal deformities (spinal curves or slippages), back pain from instability, or abnormal or excessive movement between vertebrae. Similar to the concept of welding, spinal fusion surgery uses bone grafts to join vertebrae together and eliminate or reduce movement between vertebrae.

111. In a spinal fusion procedure, the graft — usually the patient's own harvested bone (autograft) or cadaver bone (allograft) — is placed in a spacer cage within the disc space between the vertebrae during the surgery. Over the following months, a physiological mechanism similar to that which occurs when a fractured bone heals causes the graft to join, or "weld," the vertebrae together. The goal of spinal fusion is to obtain a solid fusion of the vertebrae.

112. For years, autologous bone graft has been considered the "gold standard" in fusion surgery. In an autologous bone graft — or "autograft" — the surgeon procures bone graft material from another part of the patient's body, typically from the patient's pelvis or iliac crest or from the patient's own spine (from the parts of one or more vertebrae removed to gain access to the disc space to perform the fusion), and implants the bone graft in the site where fusion is

desired. Successful fusions occur at very high rates in autograft procedures, as the harvested bone exhibits all the properties necessary for bone growth (including osteogenic, osteoconductive and osteoinductive properties).

113. As an alternative to autograft, patients can undergo an "allograft" procedure using cadaver bone instead of autograft. Although healing and fusion is not as predictable when using allograft as when using autograft (the patient's own bone), an allograft eliminates the need for the harvest procedure required in an autograft.

114. A newer option to traditional bone graft procedures is bio-engineered and bio-manufactured bone-growth materials, including INFUSE™. INFUSE™ and similar materials were thus (at least initially) appealing to many spine surgeons, since they can obviate the need for using autograft harvested from the patient's own body.

115. INFUSE™ is a genetically engineered material containing a bone morphogenetic protein ("rhBMP-2"), and is used as an alternative or supplement to autograft and allograft to help fuse the vertebrae in the spine as part of the spinal fusion surgery. The purpose of INFUSE™ is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the need to harvest bone from the patient's hip or spine.

116. MEDTRONIC'S INFUSE™ product consists of (1) a metallic spinal fusion cage (the LT-Cage™); (2) the bone graft substitute which consists of liquid rhBMP-2 (derived from Chinese hamster cells); and (3) a sponge-like carrier or scaffold for the protein (manufactured from bovine collagen) that is placed inside the fusion cage.

117. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the INFUSE™ bone graft component is used to form bone, which is intended to permanently stabilize (fuse) this portion of the spine.

118. During surgery, the rhBMP-2 is soaked onto and is intended to bind with the absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge dissolves, the rhBMP-2 stimulates the cells to produce new bone.

119. Certain bone morphogenetic proteins ("BMP"s) have been studied for decades because of their ability to heal bone and potentially decrease or eliminate the need for bone graft harvesting from other parts of the body.

120. Scientists isolated the gene for one protein (rhBMP-2) from bone tissue and used molecular biology techniques to create genetically engineered cells. These cells then produce large quantities of rhBMP-2. A similar process is used to manufacture other proteins, such as insulin.

121. Attempting to seize on this potentially lucrative opportunity to develop a new spinal fusion method, Sofamor Danek Group, Inc., a Memphis, Tennessee-based spinal device maker ("Sofamor Danek"), acquired the exclusive rights to rhBMP-2 for spinal applications in February 1995. The "rhBMP-2" liquid bone protein sold as INFUSE™ is a genetically engineered version of a naturally occurring protein that stimulates bone growth, developed as a commercially viable bone morphogenetic protein ("BMP") technology.

122. In October 1996, Sofamor Danek filed with the FDA an application for an Investigational Device Exemption to conduct a pilot study on the effects of rhBMP-2 in humans, marking the first step to obtaining approval to commercially market BMP.

123. In January 1999, MEDTRONIC purchased Sofamor Danek for $3.6 billion. On July 2, 2002, the FDA approved INFUSE™, a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, for one limited and very specific spinal fusion procedure.

124. Today, INFUSE in its entirety is a combination product, composed of a device and biologic. Infuse is a combination product because the sponge is soaked in rhBMP-2 solution and sterile water, and placed within a metal cage that acts as a place-holding scaffold. The rhBMP-2 protein promotes the new bone growth to fuse the spine, and completes the spinal fusion process.

125. The metal cage is manufactured by Medtronic in accordance with the Medical Device Quality System Regulation. The sponge is manufactured by a vendor for Medtronic, also under the Medical Device Quality System Regulation. Meanwhile, the rhBMP-2 protein is

manufactured by Wyeth and Pfizer for Medtronic, in accordance with the Center for Biologics Evaluation and Research. The sterile water is produced by a supplier in compliance with the CGMP for pharmaceuticals.

3) FDA Approval of INFUSE™.

a) The Pre-Market-Approval Process.

126. The current regulatory framework for medical device approval was established in the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. INFUSE™ is a Class III device.

127. Manufacturers such as the MEDTRONIC Defendants seeking to market Class III devices, such as INFUSE™, are required to submit a Premarket Approval Application ("PMA") that must be evaluated and approved by the FDA. The PMA requires the manufacturer to demonstrate the product's safety and efficacy to the FDA through a process that analyzes clinical and other data, including: (1) technical data and information on the product, including non-clinical laboratory studies and clinical investigations; (2) non-clinical laboratory studies that provide information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests of the device—all of which must be conducted in compliance with federal regulations which set forth, *inter alia*, criteria for researcher qualifications, facility standards and testing procedures; and (3) clinical investigations in which study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all

individual subjects, results of statistical analyses, and any other information from the clinical investigations are provided, including the results of any investigation conducted under an Investigational Device Exemption ("IDE").

128. A PMA requires that all pertinent information about the device be articulated in the application and requires the manufacturer to specify the medical device's "intended use." The indications for use required on the label are based on the nonclinical and clinical studies described in the PMA. Indications for use for a device include a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

129. In addition, each PMA submission must include copies of all proposed labeling for the device, which must comply with federal requirements. Specifically, the label must include the common name of the device, quantity of contents, and the name and address of the manufacturer, as well as any prescription use restrictions, information for use (including indications, effects, routes, methods, and frequency and duration of administration; and any relevant hazards, contraindications, side effects, and precautions), instructions for installation and operation, and any other information, literature, or advertising that constitutes "labeling" under the FDCA. Approval of the product's labeling is conditioned on the applicant incorporating any labeling changes exactly as directed by the FDA, and a copy of the final printed labeling must be submitted to the FDA before marketing.

b) INFUSE's™ Limited FDA-Approved Uses.

130. In October 1996, Sofamor Danek submitted an IDE to the FDA to study the use of rhBMP-2 as applied to an absorbable collagen sponge inserted into an LT-Cage™ interbody fusion device to treat patients with degenerative disc disease. Designed as a pilot study intended to support the initiation of a larger pivotal study, the IDE involved 14 patients—11 of whom received spinal fusion procedures using the rhBMP-2/ACS/LT-Cage™ device and 3 who received the LT-Cage™ with autologous bone—and marked the first time rhBMP-2 was used in

patients undergoing spinal fusion. In this initial clinical trial, all 11 patients who had been implanted with rhBMP-2 achieved successful fusion within six months from the time of surgery.

131. Sofamor Danek used the results of this pilot study to petition the FDA to initiate a pivotal trial of rhBMP-2 with the LT-Cage™®. This trial, which was approved by the FDA in July 1998, involved 135 investigational patients who had rhBMP-2 implanted in a single-level Anterior Lumbar Interbody Fusion (ALIF) procedure and 135 control patients who underwent the same procedure using autologous bone graft instead of rhBMP-2.

132. After acquiring Sofamor Danek in 1999, MEDTRONIC filed the INFUSE™ PMA on January 12, 2001, and was granted expedited review status by the FDA.

133. As presented in MEDTRONIC's original PMA (eventually approved by the FDA in July 2002), the initially-approved INFUSE™ product consisted of two components:

a. A specific type of spacer (the LT-Cage™ Lumbar Tapered Fusion Device) component, which is a thimble-sized hollow metal cylinder which keeps the two vertebrae in place and provides a frame that contains and directs the development of new bone growth; and

b. The INFUSE™ Bone Graft Component, which includes a collagen sponge that acts as a carrier and scaffold for the active ingredient in INFUSE™, and rhBMP-2, the actual active ingredient that is reconstituted in sterile water and applied to the collagen sponge before it is placed inside the spacer cage.

134. According to the label sought by MEDTRONIC in the PMA and subsequently approved by the FDA, INFUSE™ can only be used in an ALIF procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine.[1] ALIF is performed by approaching the spine from the front through an incision in the abdomen.

[1] While the product's label remains substantially the same as that approved by the FDA in 2002, the FDA has made minor amendments to the label through post-approval supplements. For example, on July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1. InFUSE™ has been approved by the FDA for only two other uses: certain oral maxillofacial surgeries and repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management. InFUSE™ was approved by the

135. On July 2, 2002, the FDA approved INFUSE™ to treat degenerative disc disease, but only by means of one specific procedure, namely, the ALIF procedure, and only in one-level procedures at lumbar spine levels L4 through S1.

136. Importantly, the initial approved labeling for the product indicates in bold underlined formatting: **"These components must be used as a system. The INFUSE™ Bone Graft component must not be used without the LT-Cage™ Lumbar Tapered Fusion Device component."** The labeling also directs the specific manner in which both components are to be used in a fusion procedure.

137. Despite the fact that the FDA only approved rhBMP-2 for use in the spine in combination with use of the LT-Cage™, MEDTRONIC sells INFUSE™ separately from the LT-Cage™, and has done so continuously since the approval in 2002.

138. INFUSE™ has never been approved by the FDA for use in other parts of the body or for use in any other type of procedure, other than two non-spinal uses as noted in footnote 1. Any other uses are thus, by definition, "off-label" experimental uses which are not approved by the FDA.

139. There are numerous lumbar and cervical spine surgical procedures for which INFUSE™ was not initially approved, and for which it has never subsequently been approved. No cervical fusion procedure, whatsoever, using INFUSE™ has ever been approved by FDA, regardless of the approach or procedure. The non-approved lumbar procedures include:

c. Posterior Lumbar Interbody Fusion ("PLIF"), a procedure that is used to treat nerve compression, and back pain resulting from a number of causes, involves approaching the spine from the back. PLIF, however, is a more delicate surgical approach in some respects because the spinal canal and nerves are posterior to the vertebral body, and because a surgeon must manipulate the dural sac (the membranous

FDA on March 9, 2007, for certain oral maxillofacial uses. While InFUSE™ has also been approved for treatment of certain tibial fractures and certain oral maxillofacial uses, these uses represent a very minor percentage of the product's overall sales.

sac that encases the spinal cord within the vertebral column) to perform the PLIF procedure;

d. Posterolateral Fusion ("PLF") which is similar to the PLIF procedure, but instead of removing the disc space and replacing it with a bone graft, the disc space remains intact and the bone graft is placed between the transverse processes in the back of the spine. This allows the bone to heal and stabilizes the spine by fusing the transverse process of one vertebra to the transverse process of the next vertebra; and

e. Transforaminal Lumbar Interbody Fusion ("TLIF"), which is also similar to the PLIF procedure, and is a technique utilized when an inter-body fusion is performed via a posterior approach. TLIF allows the surgeon to perform a fusion from a posterior approach without disturbing the dural sac by approaching the spine via a more lateral, or sideways, approach.

4) Off-Label Use of INFUSE™, Risks Associated with Off-Label Uses, and MEDTRONIC's Knowledge of Such Risks.

a) Generally

140. Physicians may use FDA-approved medical devices in any way they see fit — either on-label or off-label, but medical device companies are prohibited by federal law to promote off-label uses for their medical devices or to pay doctors inducements or kickbacks to promote off-label uses, or to perform procedures using the devices off-label. When a physician chooses to use a medical device in an off-label manner, he or she must inform the patient of the off-label nature of the surgery and the expected risks and benefits of such off-label use, and obtain the patient's informed consent to such use.

b) FDA's Initial Concerns with INFUSE's™ Off-Label Uses.

141. The FDA's approval of INFUSE™ was limited to one specific lumbar procedure (the ALIF procedure) due to FDA's concerns about potential adverse events in posterior uses that had already been reported at the time of the product's approval. As a result, the FDA approved

INFUSE™ for the small percentage of overall spinal fusion surgeries which are ALIF procedures, with the device label specifying this limited surgical application.

142. FDA approval of INFUSE™ was limited to ALIF only because of the number of adverse events resulting from the use of rhBMP-2 in off-label applications. In particular, a MEDTRONIC-sponsored trial examining the application of rhBMP-2 in off-label PLIF (Posterior Lumbar Interbody Fixation) procedures was halted in December 1999 when uncontrolled bone growth developed in a number of the patients. Indeed, the study reported that one patient required two additional surgeries to remove excessive bone growth from the spinal canal. Such bone overgrowth observed in this PLIF trial was particularly alarming because it could, and did in many patients, result in worsening the very pain that the fusion procedure was designed to eliminate, and in some cases necessitating difficult revision surgeries to remove the bone overgrowth.

143. Moreover, the 1999 PLIF trial demonstrated that bone overgrowth complications from INFUSE™ result from the product's very mechanism of action; i.e., rhBMP-2 stimulates the growth of new bone. Thus adverse events can result when the rhBMP-2 leaks out of the area in which bone growth is desired and/or when too much rhBMP-2 is used. In such cases, INFUSE™ can stimulate bone growth where new bone is not desired or can lead to excessive bone growth in the target area, which is often associated with other complications such as swelling, compression of nerves, and associated additional or new pain. Such unintended bone growth and swelling can be especially problematic in spinal surgeries because of the proximity to sensitive neurological structures in which INFUSE™ is used; i.e., the spinal cord and the exiting nerve roots.

144. During the FDA Advisory Committee Panel ("FDA Panel") hearing on January 10, 2002 concerning potential FDA approval of INFUSE™, Panel members voiced concerns regarding potential off-label use of the product, and asked MEDTRONIC to describe its efforts to guard against off-label use of the product.

145. In response to FDA concerns of off-label applications, one MEDTRONIC consultant, who is alleged to have received hundreds of thousands of dollars in the form of kickbacks from consulting agreements promoting INFUSE™, dismissed the FDA Panel's concerns of off-label use, stating: "this specific application before the panel today is through an anterior approach," and thus, "seems to me to be outside the scope of what we ought to be focusing on today."

146. Reiterating its concerns on off-label use, the FDA Panel cautioned MEDTRONIC to guard against procedures outside the specifically approved ALIF procedure provided in the labeled application. The FDA Panel's admonishment included concerns voiced by panel member Dr. John Kirkpatrick that off- label use could result in harm to patients. More specifically, the use of the ***tapered*** LT-Cage™ — which is difficult to implant in a posterior approach—would, if required, "prevent a majority of surgeons from applying this from a Posterior Lumbar Interbody Fusion [PLIF] perspective." In other words, the FDA explicitly warned MEDTRONIC against promoting INFUSE™ for use in off- label PLIF procedures because, according to the statements of the FDA Panel, such use could endanger patients.

147. At this 2002 FDA Advisory Committee Panel hearing, the panel members stressed concerns regarding potential off-label use of the product and repeatedly asked the MEDTRONIC presenters questions about how MEDTRONIC would seek to guard against off-label applications of the product.

148. At the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing the MEDTRONIC Defendants to guard against procedures other than the specific ALIF (anterior lumbar interbody fusion) procedure approved by the FDA.

c) <u>Off-Label Use of INFUSE™ is Dangerous and Causes Adverse Side Effects.</u>

149. The off-label use of INFUSE™ in the spine frequently causes serious adverse events. This has been known to MEDTRONIC and its key "opinion leaders" for many years.

150. The FDA Panel's initial fears in 2002 concerning the dangers of off-label use of this product were confirmed by subsequent medical studies that demonstrate that off-label use of INFUSE™ may present severe risks and dangers to patient safety.

151. For example, an early study sponsored and funded by MEDTRONIC in 1999 demonstrated an approximately 70% rate of ectopic bone growth — meaning bone overgrowth where such growth is not desired. Only a few months into this clinical trial of INFUSE™, CT scans showed unwanted bone had formed in the spinal canals of 70% of the patients treated with INFUSE™. This clinical trial, intended to include hundreds of people with degenerative disc disease, was halted after only 34 patients were treated with INFUSE™.

152. A spine surgeon who participated in this PLIF with INFUSE™ study reported that one of the patients he treated required two extra surgeries to clear the excessive bone growth from the patient's spinal canal. The complications observed in this PLIF trial were particularly serious given the potential of neural impingement (or nerve pinching) from such bony overgrowth in that procedure, potentially triggering the very sort of pain that a fusion procedure attempts to eliminate.

153. This bone overgrowth results from INFUSE™'s very mechanism of action. In such cases, INFUSE™ can stimulate bone growth where new bone is not desired and can lead to excessive bone growth into areas where bone should not be growing — *i.e.*, into or against the spinal cord or other spinal nerves.

154. There is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in the off-label procedures such as PLIF, TLIF, PLF and cervical fusions, or the expected responses to the protein in different biological environments. Indeed, many adverse events associated with the use of INFUSE™ result from off-label use of the product by surgeons who do not fully understand the highly potent nature of this molecule.

155. A study entitled, "Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures," Cahill, et al., *JAMA*, 2009 Jul 1;302(1):58-66, analyzed the integration of BMP into spinal surgeries since

2002, and the association between its use and postoperative complications, length of hospital stays, and hospital charges. Significantly, the study determined that use of bone morphogenetic proteins is associated with a substantially higher rate of complications in anterior cervical fusion procedures, which has resulted in an approximate 41% increase in hospital charges for these procedures. Notably, the study only considered complications that occurred during postoperative inpatient hospitalization immediately following the surgical procedure, and did "not include delayed complications in the outpatient setting," such as hospital readmission-related complications.

156. Such a shortcoming likely resulted in a significant understatement of the extent of complications resulting from use of bone morphogenetic proteins because, as an FDA Public Health Notification regarding complications from use of BMP in the cervical spine indicated, "[m]ost complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2." Indeed, acknowledging this fact, Dr. Kevin S. Cahill, who led the study, publicly commented, "ours is probably a bottom estimate."

157. Aside from potential understatement of complications, the study found that the rate of complications in anterior cervical fusions was 51.4% higher when using bone morphogenetic protein than in similar cases when bone morphogenetic protein was not used. These complications included increased rates of voice and swallowing-related problems, and swelling of the neck. The study's authors noted a "significantly greater" rate of complications when using bone morphogenetic proteins in these surgeries, even after considering and compensating for numerous other variables that could affect complications rates, such as age, sex, etc.

158. Astonishingly, it was not until 2004 that a paper about the disastrous 1999 PLIF trial by spine surgeons with financial ties to MEDTRONIC was finally published in a medical journal. This article inaccurately maintained that these patients were not harmed by INFUSE™. The paper (Haid, et al., *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages, The Spine Journal*, 4(5):527-

538, September 2004) downplayed the bone overgrowth complications claiming that while it showed up on CT scans, patients did not suffer ill effects. This claim was false and misleading and further encouraged dangerous off-label uses of INFUSE™.

159. In fact, David Malone, M.D., a Tulsa, Oklahoma spine surgeon involved in this 1999 PLIF clinical trial with INFUSE™, told the *Milwaukee Journal Sentinel* that two of his patients had to undergo additional surgeries because the BMP-induced bone overgrowth was painfully impinging on their nerve roots. One of the patients, a man who was in his 50s at the time, needed three operations - one for the implant, a second to remove the unwanted bone formation, and then a third when the additional bone grew back yet again.[2]

160. "It was a pretty amazing biological response," Malone said in an interview. "It grew back even larger than the first time. It got to the point that secretaries in our clinic could look at X-rays and tell who got the BMP (INFUSE™) and who did not. You could see that much bone growth."[3]

161. A May 15, 2006 medical article in *Spine* entitled "Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue" observed, "rhBMP-2 may stimulate bone growth in areas in which bone is not desired, especially as the material 'leaks' into such spaces. . . . Although this phenomenon has not been thoroughly studied, it implies that the release of rhBMP-2 into the soft tissues stimulates a rapid, potentially life-threatening, inflammatory reaction." [4]

162. Again, in a November 2006 issue of *Spine*, several authors noted a significantly increased risk of swelling from off-label use of INFUSE™ in cervical spine fusions compared to traditional fusion surgeries. Of the 234 patients studied, 27.5% of those patients treated with INFUSE™ had significant swelling after the surgery, while only 3.6% of those patients not

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[2] *See, e.g.*, "InFUSE™ Cited in Patients' Painful Bone Overgrowth: More Surgery Needed After Use, Surgeon Says," by John Fauber, *Milwaukee Journal Sentinel*, June 27, 2011.

[3] *Id.*

[4] Patel, et al, *Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue, Spine,* 31(11): 1201-1206, May 2006.

treated with INFUSE™ experienced such a complication. Further analysis demonstrated that "patients receiving rhBMP-2 were ***10.1 times more likely*** to have a swelling complication versus those who did not receive rhBMP-2." (Emphasis added.)[5]

163. A March 2007 article in *The Spine Journal* highlighted the severity of the complications associated with off-label use of INFUSE™. According to this article, five days after INFUSE™ was implanted off-label in a cervical spine fusion surgery, the implanted patient experienced serious swelling of the neck and difficulty swallowing which required emergency medical treatment such as an exploratory surgery and implantation of a breathing tube.[6]

164. A *European Spine Journal* article in August 2007 found that use of INFUSE™ in certain cervical spine fusions resulted in a statistically significant increase in the number of complications, including dysphagia (difficulty in swallowing) and swelling in the neck area. The authors determined that "[d]ysphagia was a common complication and it was significantly more frequent and more severe in patients in whom rhBMP-2 was used. Post-operative swelling . . . was significantly larger in the rhBMP-2 group." Of the patients evaluated, 85% of those treated with INFUSE™ reported difficulty swallowing after the surgery; a complication that was far less severe in those not treated with INFUSE™. Indeed, one patient required a feeding tube for six weeks after the surgery as a result of the complication. [7]

165. On July 1, 2008, the FDA issued a Public Health Notification to healthcare practitioners entitled "Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion" (the "FDA Notification"), which

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[5] Smucker, et al., *Increased Swelling Complications Associated with Off-Label Usage of rhBMP-2 in the Anterior Cervical Spine, Spine,* 31(24): 2813-2819, November 2006.

[6] Perri, et al., *Adverse Swelling Associated with Use of rh-BMP-2 in Anterior Cervical Discectomy and Fusion: A Case Study, The Spine Journal,* 7(2): 235-239, March 2007.

[7] Vaidya, et al., *Complications of Anterior Cervical Discectomy and Fusion Using Recombinant Human Bone Morphogenetic Protein-2, European Spine Journal,* 16(8): 1257-1265, March 2007.

strongly warned medical professionals who used INFUSE™ and other BMP products of serious complications that had occurred from the off-label use of these products in the cervical spine.[8]

166. The FDA Notification stated that the agency had received numerous reports of complications from BMP use in the cervical spine that "were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking." The notification further stated that these complications had resulted in "the need for emergency medical intervention," which included "respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site." The FDA Notification concluded that "in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies."

167. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "MEDTRONIC Product Linked to Surgery Problems."[9] This article noted both the complications resulting from the use of INFUSE™ in the cervical spine already disclosed in the FDA Notification and additional complications resulting from other off-label applications of the product, stating:

> The FDA's alert about INFUSE™ was specific to neck surgeries. But a review of FDA records and medical literature shows there have been scores of other cases in which serious complications arose after the product was used in other off-label situations. Many of these cases involve unwanted bone growth near nerves or in areas outside targeted fusion sites. That can lead to pain, repeat surgeries and, in some cases, emergency intervention.

The article further stated that at least three-quarters, or 75%, of the adverse events reported to the FDA involved off-label use of INFUSE™. Of course, this news had serious implications for

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[8] FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion, July 1, 2008, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm

[9] "Medtronic Product Linked to Surgery Problems," by David Armstrong and Thomas M. Burton, *Wall Street Journal*, September 4, 2008.

MEDTRONIC because off-label use of INFUSE™ accounted for the majority of all INFUSE™ sales.

168. A September 2008 article in *The Spine Journal* also observed that the use of INFUSE™ in the cervical spine "has been associated with reports of serious adverse events.[10] Postoperative hematoma formation [a collection of blood outside the blood vessels, generally manifesting as bruises], prevertebral soft tissue swelling, [and] swallowing difficulty . . . are a few examples." Of the complications observed in this patient study group, 17% occurred in patients treated with traditional techniques, while 83% occurred in patients treated off-label with INFUSE™. The authors concluded that the "cervical spine has proven much less forgiving with the institution of rhBMP-2 use. Complications induced by . . . rhBMP-2 were clearly evident in our review."

169. On November 18, 2008, in connection with reporting MEDTRONIC's financial results for its 2009 second quarter (ended October 24, 2008), MEDTRONIC reported that revenue from its Spinal segment had, in fact, declined to $829 million for the quarter – down $30 million from the previous quarter. The decreased sales in the Spinal segment, clearly stemming from a significant decline in INFUSE™ sales, were a sharp deviation from MEDTRONIC's reports of repeated, double-digit, growth in the Spinal segment in previous quarters. Moreover, MEDTRONIC disclosed, for the first time, that it "recently received a subpoena from the Department of Justice looking into off-label use of INFUSE™."

170. Thereafter, MEDTRONIC continued to report lower sales of INFUSE™, which it admittedly linked to a public health notice from the FDA regarding off-label use of recombinant human bone morphogenetic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories, and a whistleblower lawsuit filed by two former MEDTRONIC employees against MEDTRONIC and a number of spine surgeons and distributors of the INFUSE™ bone graft.

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[10] Jarosz, et al., *Complications of BMP Use in Cervical Spine Surgery, The Spine Journal,* 8(5): 23S-24S, September 2008.

171. The use of INFUSE™ in off-label procedures was further scrutinized in a study published in the July 1, 2009 issue of JAMA that documented the health risks associated with off-label use of INFUSE™ and, contrary to previous studies conducted by MEDTRONIC-funded physicians, cast doubt on the cost-effectiveness of the product.[11]

172. At least 1,200 reports of adverse events involving INFUSE™ have been made to the FDA from 2002 to 2011. In 2011, for example, 278 INFUSE™-related adverse events were reported; in 2010, 362 adverse events were reported; and in 2009, 244 adverse events were reported. The vast majority of these adverse event reports involve off-label use of INFUSE™.

173. In fact, in a 2012 article published in The Spine Journal, FDA researcher Emily Woo, M.P.H. concluded on-label use of INFUSE™ accounts for only a tiny percentage (0.5%) of adverse events. Off-label use of INFUSE™ accounts for 99.5% of adverse events.[12]

174. The number of INFUSE™-related adverse events is growing steadily over the years, and the proportion of off-label adverse events grows, as well, as a direct result of the MEDTRONIC Defendants' long-standing campaign of improper off-label promotion of the more dangerous off-label uses of INFUSE™ which were never approved by the FDA. The extent of these adverse events was, at all relevant times, hidden or downplayed by MEDTRONIC and its paid consultants.

d) MEDTRONIC's Prior Knowledge and Concealment of the Dangers of Off-Label INFUSE™ Uses.

175. Even at the time of FDA approval, MEDTRONIC and its senior management and its paid consultant "opinion leaders," were well aware of the concerns regarding off-label uses of INFUSE™ and the serious dangers to patients posed by those off-label uses.

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[11] Cahill, et al., *Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures, JAMA*, 302(1): 58-66, July 2009.

[12] Emily Jane Woo, *Recombinant Human Bone Morphogenetic Protein 2: Adverse Events Reported to the Manufacturer and User Facility Device Experience Database, The Spine Journal*, 12(10): 894-899, October 2012.

176. Notwithstanding the original FDA Panel's well-founded concerns regarding off-label use, as well as the medical literature's corroboration of the same, both of which MEDTRONIC had knowledge, MEDTRONIC intentionally, negligently and recklessly concealed these dangers from the general public, including the Plaintiffs and Plaintiffs' physicians.

177. MEDTRONIC had actual knowledge of the Advisory Committee's concerns regarding off-label use of the product and the dangers posed by off-label use. Indeed, Defendants were on actual notice at this time of the Advisory Committee's warnings that MEDTRONIC should guard against off-label uses of this potent genetically-engineered liquid bone protein. Thus, even *prior* to FDA approval, Defendants were on actual notice of the dangers that off-label use of INFUSE™ posed to patients, such as the Plaintiff.

178. Further, as described immediately *infra*, the MEDTRONIC-funded studies on INFUSE™ from 1999 to until at least 2007 failed to accurately describe the adverse effects that were observed in the earliest trials of INFUSE™, such as severe uncontrolled or ectopic bone growth, severe inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement. These MEDTRONIC-funded articles also omitted any mention of the risks of sterility and cancer associated with rhBMP-2 use, as reported in FDA documents and hearings. MEDTRONIC discouraged the publication of these results in the medical journal literature, thereby hiding significant side effects from spine surgeons and patients.

179. Further, Confidential Witness #2 ("CW 2") in a shareholder derivative lawsuit filed against MEDTRONIC, more fully discussed *supra*, stated that MEDTRONIC was aware of adverse events resulting from off-label use of INFUSE™ in the cervical spine, including swallowing, and breathing problems.

180. In response to these reports of adverse events, CW 2 stated that MEDTRONIC attempted to disseminate information to the medical community regarding what it considered to be the proper dose of INFUSE™ for this off-label application. MEDTRONIC also issued a

"Safety Alert" letter to surgeons on September 14, 2004, informing them that MEDTRONIC had received reports of complications associated with off-label use of INFUSE™ in anterior cervical fusion procedures. MEDTRONIC wrote, "***[l]ocalized soft tissue edema has been reported in anterior cervical spine fusion surgery following the use of INFUSE™ Bone Graft…. Some reports were accompanied by patient complaints of swelling and difficulty in swallowing and breathing, three of which resulted in surgical intervention.***" (Emphasis added.)

181. These adverse events were not isolated incidents, as described above. These adverse event reports from off-label uses of INFUSE™ indicate the very same complications as those noted in the studies discussed above, including, swelling, difficulty swallowing and breathing, excessive bone growth resulting in dangerous and painful spinal nerve compression and corresponding injuries, etc., and often require emergency medical intervention or a second surgery.

182. For example, a December 12, 2005 report indicates that four or five days after an off-label PLIF procedure using INFUSE™, the patient's swelling became so severe that surgical intervention was required.

183. A November 3, 2006 report indicates that a patient reported neck swelling, difficulty swallowing and possible shortness of breath two to three days after a cervical spine fusion using INFUSE™. As a result, this patient had to undergo another surgery four days after the initial fusion.

184. A July 21, 2008 report indicates that a patient developed massive neck swelling, very thick tracheal and bronchial secretions, and required a tracheostomy—a procedure in which an incision is made in the neck and a tube inserted to allow the patient to breathe—following a cervical fusion procedure with INFUSE™. These are only a few examples of the hundreds of similar reports of serious complications related to off-label uses of INFUSE™ found on the MAUDE Database.

185. Through MEDTRONIC's monitoring procedures—which include written procedures for complaints, corrective and preventative actions and adverse event reporting—all

complaints and adverse events are documented, tracked, and trended (or should be) in a database. MEDTRONIC is required by federal regulation to "establish and maintain" such an adverse event database. *See* 21 C.F.R. § 803.1(a). In addition, a report from a June 2006 FDA inspection of a MEDTRONIC facility at 1800 Pyramid Place in Memphis, Tennessee, revealed that MEDTRONIC had initiated a Preventative Action, dated April 21, 2006, and was "studding [sic] the reason for an increase in the number of reported fluid collection, hematoma, and seroma complaints since 4/2005." According to the report, the "study indicated that sales for the INFUSE™ Bone Graph [sic] have increased and more graphs [sic] are being implanted," and that the "study is still open."

186. According to Confidential Witness #15 ("CW 15") in the *Minneapolis Firefighters* lawsuit filed against MEDTRONIC, more fully discussed *supra*, a Senior Vice President who worked at MEDTRONIC for numerous years until 2006 and a "Quality Group" at MEDTRONIC's Spine division were responsible for addressing adverse events. According to CW 15, former COO Michael DeMane, former President of MEDTRONIC Spinal and Biologics Mr. Wehrly, and former Worldwide Vice President and General Manager, Biologics, Jon Serbousek, were all aware of the adverse events related to INFUSE™. As a part of his employment with Defendants, CW 15 discussed the complaints related to INFUSE™ at meetings with these individuals and members of the Quality Group to decide whether or not certain adverse events should be reported to the FDA. Moreover, MEDTRONIC's Spinal division used the very same complaint/adverse event reporting system as MEDTRONIC corporate, which provided MEDTRONIC's executive officers access to a database containing details of every complaint/adverse event MEDTRONIC received relating to INFUSE™.

187. MEDTRONIC was further clearly aware of its settlement with the Department of Justice ("DOJ") and entry into a Corporate Integrity Agreement, discussed *supra*, in July of 2006. As a result, MEDTRONIC had actual knowledge of the heightened risks to spine patients associated with MEDTRONIC's illegal, improper, and unethical promotion of off-label use of INFUSE™ by MEDTRONIC's Spinal or Biologics Divisions.

5) INFUSE™ is Profitable and thus MEDTRONIC had an Economic Motive to Promote INFUSE™ Off-label.

188. INFUSE™ has become a best seller for MEDTRONIC. MEDTRONIC's INFUSE™ sales have exceeded $3.6 billion since the launch of the INFUSE™ Bone Graft in July 2002. As a J.P. Morgan research analyst covering MEDTRONIC noted in a report dated November 12, 2008:

> INFUSE™ is an $800M product for MEDTRONIC (6% of sales), having enjoyed robust growth since its initial approval in the U.S. in July 2002. In fact, it is the one piece of MEDTRONIC's Spine business that continues to post strong double-digit growth without any issues (LTM: +16.9%). That is, until now.

189. MEDTRONIC has depended heavily on INFUSE™ sales because so many of its other products, such as cardiac defibrillators, have slowed as the result of recalls of those defective defibrillators in the past several years.

190. Revenue generated by sales of INFUSE™ was approximately $800 million for the 2011 fiscal year, and the vast majority of these sales were attributable to off-label use of the product. Off-label uses of INFUSE™ account for 85% to 90% of all spine surgeries involving INFUSE™.

191. Plaintiffs are informed and believe and based thereon allege that, as a result of MEDTRONIC's illegal and improper off-label promotion, sales of INFUSE™ have soared and have totaled more than 4 billion of dollars from 2002 to 2011.

192. MEDTRONIC has consistently sought to expand the use of INFUSE™ by, among other things, illegally and improperly promoting dangerous and/or insufficiently studied off-label uses for INFUSE™ in various parts of the spine for various types of spine surgeries, as discussed throughout this Complaint.

6) MEDTRONIC Improperly Promoted Off-Label Uses of INFUSE™.

a) Generally

193. In spite of the very specific and limited FDA approval of INFUSE™ (for ALIF procedures only), the overwhelming majority of MEDTRONIC's INFUSE™ sales have been

driven by non-FDA approved, or "off-label," uses, such as that used on the Plaintiffs in this civil action. Until recently, MEDTRONIC was very successful (and profitable) in driving off-label sales of INFUSE™ through undisclosed "consulting" and royalty agreements with physicians who, in exchange for handsome sums of money from MEDTRONIC or lavish trips paid for by MEDTRONIC, would push off-label usage in a number of ways, including by authoring scientific and medical literature promoting such uses, and by direct advocacy to other spine surgeons.

194. MEDTRONIC also directed its own sales representatives to promote off-label uses of the product, many of whom went so far as to recommend dosages of this potent molecule in risky off-label procedures, and guide surgeons through off-label uses of the product during surgery. Indeed, MEDTRONIC's unlawful off-label promotion campaign was so extensive that it caught the attention of, among others, the FDA (on numerous occasions), the United States DOJ, Congress, the United States Army, several major universities, multiple medical journals, numerous major newspapers, independent physicians, and investors.

195. Moreover, MEDTRONIC's unlawful off-label campaign has resulted in, among other actions, two whistleblower lawsuits (resulting in a multi-million dollar settlement with the DOJ, which included a Corporate Integrity Agreement), a shareholder derivative lawsuit that was recently settled for $85 million, several adverse regulatory actions by the FDA, and a congressional investigation (led by the United States Senate Committee on Finance).

196. Indeed, even following MEDTRONIC's settlement with the DOJ in 2006 for unlawful kickbacks to physicians to use and promote its products, and corresponding entry into a Corporate Integrity Agreement ("CIA"), discussed *supra*, MEDTRONIC failed to disclose its continued reliance on kick-backs, royalties, and other undisclosed payments to physicians to drive INFUSE™ sales, primarily for off-label use.

197. Off-label use of INFUSE™ was and remains particularly concerning due to the known adverse (and in at least one case deadly) side effects known to MEDTRONIC at the time of the product's original FDA approval in 2002. Nonetheless, off-label use of INFUSE™

increased year-after-year from the time of its original limited use approval by the FDA in 2002, to the point where off-label use of INFUSE™ Bone Graft accounted for an astounding 85% to 90% of all INFUSE™ sales.

198. Although undisclosed by MEDTRONIC, the first-hand accounts of its former employees demonstrate that this extraordinarily high off-label use was driven by MEDTRONIC's sales force. Specifically, MEDTRONIC's marketing and sales employees directed spine surgeons to MEDTRONIC-compensated consultants or "Opinion Leaders" or "Thought Leaders" – other spine surgeons paid by enormous sums of money by MEDTRONIC – the sole purpose of which was to promote off-label uses of INFUSE™. Through these and other illegal and improper practices, MEDTRONIC was able to increase INFUSE™ sales year after year while continuing to hide and downplay the product's dangerous side effects when used off-label in the spine.

199. MEDTRONIC actively promoted off-label use of INFUSE™ through its sales representatives and massive payments to its "Opinion Leader" spine surgeon consultants, which included sponsoring presentations at continuing medical education courses, and appearances at consulting engagements promoting off-label applications of INFUSE™. In turn, MEDTRONIC's sales force directed other physicians to these consultants and "Opinion Leaders" or to their written work (paid for by MEDTRONIC) to further drive off-label sales of INFUSE™. Indeed, MEDTRONIC engaged in such conduct even after its settlement of the whistleblower action with the DOJ in which it agreed to employ stricter compliance controls regarding the sale and marketing of its spine products.

200. The MEDTRONIC Defendants, while providing spine surgeons with MEDTRONIC-funded studies and published articles purporting to support the efficacy and safety of the off-label uses, simultaneously and systematically concealed or downplayed other non-MEDTRONIC-funded studies and articles demonstrating serious and frequent adverse events caused by the same off-label uses.

201. Several spine surgeons have already testified under oath at depositions that MEDTRONIC sales personnel overtly and directly promoted to them the off-label uses of INFUSE™ in the spine, and Plaintiffs are thus informed and believe that MEDTRONIC engaged in a scheme at all relevant times to expand its market share of this product by improperly encouraging such off-label uses.

202. In this particular case, MEDTRONIC actively promoted the off-label procedures to Plaintiffs' spine surgeon, and Plaintiffs' spine surgeons would not have performed the off-label INFUSE™ procedure in the absence of such promotion. MEDTRONIC's off-label promotion of INFUSE™ to Plaintiffs' surgeon was false and misleading, in that it overemphasized the purported benefits of the off-label use, and hid, minimized, or downplayed the true risks and dangers of the off-label use, all of which were known to MEDTRONIC at all relevant times.

b) Off-label Promotion of INFUSE™ Violates the Food, Drug, and Cosmetic Act.

203. The FDCA specifically provides that the FDA has no authority to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship," and physicians are free to prescribe or use medical devices in any manner they deem medically appropriate. 21 U.S.C. § 396.

204. Importantly, however, medical device manufacturers such as MEDTRONIC cannot actively promote products for uses not approved by the FDA. Indeed, federal law provides for significant penalties for manufacturers that promote their products in ways inconsistent with a product's labeling. Severe penalties for off-label promotion, such as fines of up to twice the amount of the gross pecuniary gain from the offense, were designed to ensure that the FDA's careful, deliberate consideration of a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process. The MEDTRONIC Defendants are medical device companies, not physicians, and they are prohibited by federal law

including the relevant FDA regulations, at all relevant times, from promoting to physicians or patients any off-label use of INFUSE™.

205. Under the FDCA and its accompanying regulations, a device manufacturer must include all intended uses in the label, otherwise the device is misbranded. 21 C.F.R. §801.4. Under the FDCA, device manufacturers can be held liable for off-label promotion when their products are deemed "misbranded" under the statute. 21 U.S.C. § 331(b).

206. A product is "misbranded" when the directions and indications for the unapproved uses that the manufacturer "intends" the product to be used for have not been included on the label. *See* 21 C.F.R. §801.4. Further, a device's intended uses are evidenced by the manufacturers' conduct, not by reference to what the FDA has approved. *Id.* A product's intended uses can be derived from oral statements by persons speaking on behalf of a company about its product. In other words, a manufacturer can be liable under the FDCA if its conduct demonstrates intent to encourage product use inconsistent with or outside the scope of the product's approved label. *Id.*

207. The FDCA's accompanying regulations require that medical devices sold by manufacturers have adequate directions for use, 21 C.F.R. § 801.5, and failure to have adequate instructions for use is considered "misbranding," 21 U.S.C. § 352(f), which is prohibited. 21 U.S.C. § 331(b).

208. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling,[13] 21 U.S.C. § 321(n), and false or misleading labeling is considered "misbranding," 21 U.S.C. § 352(a), (q)(1), which is prohibited. 21 U.S.C. § 331(b).

209. Further, the FDCA requires medical device manufacturers to maintain and submit information as required by regulation, 21 U.S.C. § 360i, including submitting adverse event reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports. 21 C.F.R. § 820.198(a).

[13] 21 U.S.C. §321(m) defines the scope of medical device labeling.

210. MEDTRONIC violated the FDCA statutes and accompany regulations by promoting INFUSE™ for off-label uses, and by failing to account for adverse events and update its labeling, directions for use, and advertising to account for the adverse events resulting from these off-label uses.

211. MEDTRONIC's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth below.

212. MEDTRONIC's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the off-label use of INFUSE™ generally, and directly caused or significantly contributed to the off-label use of INFUSE™ in this particular Plaintiff, and MEDTRONIC's misconduct in this regard thus caused or contributed to Plaintiff's injuries and damages.

c) MEDTRONIC Settles Whistleblower Litigation with the DOJ and Agrees to Enter into a Corporate Integrity Agreement

213. The MEDTRONIC Defendants were named as defendants in two *qui tam* actions, *United States ex rel. (UNDER SEAL) v. MEDTRONIC. Inc., et al.*, Civil Action No. 02-2709 (W. D. Tenn. 2002) (hereinafter "*[Under Seal]*"), and *United States ex rel. Poteet v. MEDTRONIC, Inc., et al.*, Civil Action No. 03-2979 (W. D. Tenn. 2003) (hereinafter "*Poteet I*"), (collectively the "qui tam lawsuits"), both of which alleged that MEDTRONIC violated the False Claims Act, 31 U.S.C. § 3729, *et seq.*, by paying illegal kickbacks to physicians in connection with promoting the off-label use of INFUSE™ in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

214. Based on its investigation, the DOJ contended that certain of the payments, services, and remuneration mentioned above were improper and resulted in the submission of false or fraudulent claims in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq.*, which prohibits individuals from offering, soliciting or making any payment or remuneration to induce business reimbursed under a federal or state health care program, and the

False Claims Act, 31 U.S.C. § 3729, *et seq.*, which provides penalties for the submission of false claims to the federal government. Both *[Under Seal]* and *Poteet I* were brought by MEDTRONIC's former employees who made these allegations.

215. In these lawsuits, the DOJ contended that between January 1, 1998 and April 30, 2003, MEDTRONIC made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for physicians' attendance and expenses at medical education events, "think tanks," VIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians through MEDTRONIC's Healthcare Economic Services and eBusiness Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities.

216. Specifically, *[Under Seal]* was brought by a former MEDTRONIC in-house counsel, who alleged that MEDTRONIC's "aggressive and illegal" sales and marketing efforts were intended by MEDTRONIC to improperly induce physicians to use MEDTRONIC's Spinal products, including INFUSE™. The conduct alleged included, *inter alia*: (1) lucrative consulting and royalty agreements with physicians that used MEDTRONIC Spinal products, "the true purpose [of which were] to funnel money to the physicians so that they will be induced to use [MEDTRONIC Spinal] products;" and (2) "[l]avish all-expense paid trips to fine resorts . . . disguised as Medical Education seminars, think tanks, or discussion groups . . . held in places such as Hawaii, Cancun, Alaska, Beaver Creek, Whistler, Malaysia, Amelia Island, Teton Valley, and New Orleans at Mardi Gras . . . [t]he purpose of these lavish trips was to induce the physicians to use [MEDTRONIC Spinal] products."

217. The complaint further alleged that: "Most of the illegal kickback practices described herein were begun by Sofamor Danek and continued by [MEDTRONIC] after the acquisition. Kickbacks were the culture and way of doing business at Sofamor Danek and the company was determined to continue that culture, and did continue that culture, when Sofamor Danek became part of the MEDTRONIC empire."

218. *Poteet I* brought by a former MEDTRONIC employee who was tasked by MEDTRONIC to arrange travel (including expense reimbursement) for numerous spinal surgeons to attend MEDTRONIC-sponsored events and other professional meetings. This former employee also alleged that MEDTRONIC paid surgeons substantial fees—sometimes up to hundreds of thousands of dollars per year—for consulting services that were grossly in excess of their fair market value, entered into royalty agreements that were designed to disguise illegal remuneration, and provided physicians opportunities for lavish travel and recreational activities, including "upgraded lodging for physicians, dinners, entertainment and activities such as golf, snorkeling, sailing, fishing, shopping trips, [and] horse-back riding" for using MEDTRONIC products. These consulting agreements and other payments were illegitimate means of inducing physicians to use MEDTRONIC products and to recommend to other physicians that they do the same.

219. On July 18, 2006, MEDTRONIC agreed to pay $40 million to the United States of America to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12.

220. As part of the DOJ settlement, MEDTRONIC agreed to enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General/Health and Human Services that, as MEDTRONIC described in its July 18, 2006 press release, implemented substantial oversight structures and procedures meant to ensure "top-level attention to corporate compliance measures." Among other things, the CIA required MEDTRONIC to establish an electronic database to capture and manage all non-sales related transactions between MEDTRONIC's Spinal segment and its physicians or customers, with all such transactions subject to an established set of internal controls and review processes, including monitoring by MEDTRONIC senior management and MEDTRONIC's Chief Compliance Officer.

221. Moreover, the CIA required MEDTRONIC to implement internal policies and procedures to ensure stricter regulatory compliance, which obligated MEDTRONIC to institute a number of changes to improve oversight of its Spinal division.

222. Significantly, the CIA required MEDTRONIC to adopt procedures to ensure that any "arrangements"—a term intended to cover physician consulting agreements and broadly defined as engagements involving "directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; [] between [MEDTRONIC] and any actual or potential source of health care business [e.g., physicians]"—would not violate federal law. Such procedures were to include, among other things: (1) creating a database of all existing and new or renewed arrangements; (2) tracking remuneration from MEDTRONIC to all other parties to such arrangements; (3) tracking service and activity logs to ensure that parties to an arrangement are performing their duties under the applicable arrangement; (4) implementing procedures that ensure all arrangements are reviewed for adherence to the Anti-Kickback Statute; and (5) regular (at least quarterly) review by the MEDTRONIC Compliance Officer of the arrangements database along with reporting (at least quarterly) to the MEDTRONIC Compliance Committee.

223. The CIA and the previous whistleblower and wrongful termination litigation placed MEDTRONIC and its agents on actual notice that its practice of marketing, and promoting INFUSE ™ for off-label uses was improper and required wholesale change to avoid further adverse regulatory action or other liability.

224. As a result of this settlement, MEDTRONIC agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which MEDTRONIC agreed to a settlement concerning the conduct at issue in the False Claims lawsuits.

225. Nonetheless, MEDTRONIC's unlawful practices continued, as did MEDTRONIC's aggressive efforts to drive INFUSE™ sales by promoting off-label applications, such as precisely those used on the Plaintiff. MEDTRONIC has continued to improperly and

illegally promote the off-label use of INFUSE™ for non-FDA-approved uses of the product. Indeed, it was motivated to do so knowing that, absent off-label use, sales of INFUSE™ would dramatically decline. In order to prevent a decline in sales revenue, MEDTRONIC continued to covertly employ the same lucrative "consulting" arrangements and other unlawful conduct to promote off-label uses of INFUSE™.

226. As a result of MEDTRONIC's undisclosed misconduct, the percentage of off-label INFUSE™ usage increased over time, including after the DOJ settlement on July 14, 2006. By 2011, off-label use of INFUSE™ constituted more than 90% of the total use of INFUSE™ in spinal fusion procedures.

227. Indeed, MEDTRONIC's unlawful marketing and promotion was so effective that a MEDTRONIC analyst from Bernstein Research noted in a November 21, 2006 report that analysts were "expecting *continued indication expansion (e.g., recent dental approval and likely approval for posterior lateral fusion) for INFUSE™ to be the main driver for the spinal business* in the mid-term." (Emphasis added.) What this analyst and the public at large did not know was that, despite the limited FDA-approved applications of INFUSE™, MEDTRONIC continued to drive sales solely through off-label indications; and was doing so in spite of the CIA, the material risk of further regulatory action or other liability, and in conscious disregard for the health and welfare of spine patients such as the Plaintiff.

d) Testimony of Former Medtronic Employees Regarding Off-label Promotion of INFUSE™ in a Shareholder Derivative Action Against Medtronic.

228. A federal securities lawsuit filed on behalf of the Minneapolis Firefighters' Relief Association against MEDTRONIC, *Minneapolis Firefighters' Relief Assoc. vs. MEDTRONIC, Inc.*, Civil No. 08-6324 (PAM/AJB) (D.Minn., 2009), also alleged evidence of MEDTRONIC's egregious campaign of off-label promotion of INFUSE™, even after the CIA. MEDTRONIC's actions, described by the "Confidential Witnesses" ("CW"), included:

a. MEDTRONIC-sponsored physician meetings, during which MEDTRONIC would employ paid consultants – typically surgeons hand selected by

MEDTRONIC – to present off-label presentations to local physicians. CW1, Consolidated Class Action Complaint dated August 21, 2009, at ¶ 93.

b. MEDTRONIC's instructions to its sales representatives regarding various off-label uses of INFUSE™, including how much of the biologic to use with off-label cervical fusions, the purpose of which was to instruct physicians regarding off- label uses. CW1, *Id.* at ¶ 94.

c. MEDTRONIC's directions to its sales representatives that they be present during off-label INFUSE™ surgeries "to assist and direct and give advice when asked." CW1, *Id.* at ¶ 95; CW2, *Id.* at ¶ 97; CW5, *Id.* at ¶ 101; CW6, *Id.* at ¶ 102.

d. MEDTRONIC's creation of sales quotas that were described by the CWs as impossible to reach without pushing off-label use. CW1, *Id.* at ¶ 95; CW9, *Id.* at ¶ 105; CW11, *Id.* at ¶ 107; CW12, *Id.* at ¶ 108.

e. MEDTRONIC sales representatives' references to data from published literature (presumably funded by MEDTRONIC) when questioned by surgeons, the purpose of which was to provide surgeons with information regarding proffered techniques for off-label procedures and to educate them regarding off-label uses. CW2, *Id.* at ¶ 96.

f. MEDTRONIC's development of smaller-sized Bone Graft kits under the guise of selling them for FDA-approved uses, when, in actuality, MEDTRONIC had designed them to be used in off-label cervical fusion surgeries. CW2, *Id.* at ¶ 97; CW7, *Id.* at ¶ 103.

g. Moreover, by comparing the number of units of rhBMP-2 with the sales of the LT-Cage™ component – which were packaged and sold separately – CW2, 11, and 12 determined that the driving force behind MEDTRONICs $750 million in sales of INFUSE™ was solely attributable to off-label uses. Although the FDA required the rhBMP-2 and LT-Cage™ to be used together, sales of the rhBMP-2

component greatly outpaced those of the LT-Cage™. component. CW2, *Id.* at ¶ 98; CW11, *Id.* at ¶ 107; CW12, *Id.* at ¶ 108.

h. When questioned by a physician about how to use INFUSE™ off-label, MEDTRONIC sales representatives directed physicians to other surgeons who used the product off-label and also would demonstrate or explain how to do so. CW3, *Id.* at ¶ 99; CW5, *Id.* at ¶ 101; CW6, *Id.* at ¶ 102; CW10, *Id.* at ¶ 106; CW11, *Id.* at ¶ 107.

i. MEDTRONIC held quarterly meetings in at least one sales region, during which a national biologics specialist would attend to explain how to conduct off-label applications of INFUSE™. CW3, *Id.* at ¶ 99.

j. MEDTRONIC directed its sales representatives to instruct physicians to use half the dose of rhBMP-2 during cervical fusion, and MEDTRONIC, aware of adverse events, instructed the representatives to tell physicians to use steroids to combat potential inflammation. CW4, *Id.* at ¶ 100; CW5, *Id.* at ¶ 101.

k. MEDTRONIC directed physicians using the product in cervical spine fusion to throw away a large portion, sometimes up to half, of the rhBMP-2 dosage. CW6, *Id.* at ¶ 102.

l. MEDTRONIC gave to physicians a small book containing no reference to MEDTRONIC, which contained information regarding the volume or dosage of rhBMP-2 that should be used for off-label applications of INFUSE™. CW7, *Id.* at ¶ 103; CW8, *Id.* at ¶ 104; CW9, *Id.* at ¶ 105.

m. MEDTRONIC instructed CW8 and others during sales presentations regarding how to "get around" restrictions on off-label promotion. CW8, *Id.* at ¶ 104.

n. CW13 was brought into MEDTRONIC to develop a marketing plan; which included: a) Development of a "referral marketing" campaign designed to promote the product for off-label uses via a physician referral network; b)

identifying which surgeons would be targeted as part of MEDTRONIC's off-label campaign and what claims MEDTRONIC would make about the product; c) development of a "cookie- cutter" CD series that outlined MEDTRONIC's off-label campaign and included information on off-label procedures that was distributed to MEDTRONIC sales representatives. According to CW13, the referral marketing program involved having surgeons meet with other surgeons as a means of prompting discussion of off-label uses of INFUSE™ Bone Graft among practitioners. CW13 also stated that MEDTRONIC used a physician training program involving cadaver labs as a means to instruct surgeons regarding off-label applications. CW13, *Id.* at ¶ 109.

o. CW13 was rebuffed for raising concerns about off-label promotion, and was told "we're paying you a lot of money to launch this. Shut your mouth and take the money. Let us worry about what is off-label or isn't." CW13, *Id.* at ¶ 110.

p. A sales representative was present in the operating room during an off-label cervical procedure which led to the patient's death. The patient's family subsequently initiated civil litigation against MEDTRONIC and the sales representative who was allegedly encouraging the off-label procedure at MEDTRONIC's behest. *Id.* at ¶ 111.

q. Although MEDTRONIC is under an obligation to report all serious adverse events associated with INFUSE™, MEDTRONIC failed to report the death of this patient until three months after it occurred. FDA guidelines recommend that a manufacturer make a minimum of three attempts to retrieve additional information regarding any adverse event. While the company filed an adverse event report with the FDA in which it noted the complications immediately following the procedure, MEDTRONIC did not inform the agency of her death until after a lawsuit was filed by the patient's family and reported in *The Wall Street Journal*. *Id.* at ¶ 112.

r. In a separate civil suit against MEDTRONIC, a physician admitted to attending numerous national spine meetings during which off-label uses of rhBMP-2 in the cervical spine were promoted. A MEDTRONIC sales representative was in the operating room a lot when he was performing off-label uses. He admitted to doing over 100 cervical procedures, insinuating that the MEDTRONIC sales representative was in the room for a fair number of these procedures. *Id.* at ¶ 113.

229. The plaintiffs in the *Minneapolis Firefighters* lawsuit also discovered the growing percentage of off-label INFUSE™ usage from 2003-2007 by analyzing surgical procedural codes used by hospitals.[14] The results of this analysis demonstrate that off-label usage of INFUSE™ was high, even from the inception of FDA approval, and increased by an astonishing 10% over the next 4 years; to wit:

Year	Estimated On-Label Procedures	Estimated Off-Label Procedures
2003	25.7%	74.3%
2004	20.6%	79.4%
2005	15.8%	84.2%
2006	15.3%	84.7%
2007	14.8%	85.2%

230. Moreover, the data further demonstrate that off-label use of INFUSE™ in the cervical spine grew to as much as 18% of overall INFUSE™ use as of 2007, despite the known increased medical risks associated with that application.

231. Indeed, to set sales projections for INFUSE™, CW 2 stated that MEDTRONIC's marketing department accounted for the scope and number of procedures performed, including the numbers of off-label procedures, such as PLIFs and TLIFs, to predict sales projections. This analysis was based, in part, on data purchased from market research companies demonstrating the number of procedures involving different areas of the spine, e.g., certain lumbar (on- or off-

[14] The methodology employed was consistent with a July 1, 2009 report in the JAMA that conducted a retrospective cohort study of 328,468 patients undergoing spinal fusion procedures from 2002-2006, using the same codes from the NIS database.

label) versus cervical (off-label). Once MEDTRONIC determined its sales projections, these figures were incorporated into a budget presented to MEDTRONIC's senior management. Importantly, the final sales quotas for INFUSE™ were dictated by MEDTRONIC senior management, and were far in excess of what MEDTRONIC's Spinal Division had projected, or could be achievable absent promotion of the product for off-label uses. According to CW 2, "when the numbers came back down, they never reflected the projections. They were much larger."

232. Numerous confidential witnesses, including CWs 1, 9, 12 and CW 14 (a senior manager for MEDTRONIC's Spinal and Biologics division from 2005 to 2008), confirm the intense pressure MEDTRONIC's management placed on its sales representatives to meet the sales quotas the company set. Like CW 2, CW 14 explained that sales goals were set by a handful of MEDTRONIC executives, and that they were "very, very, very aggressive." Likewise, CW 12 stated that there was a lot of pressure on MEDTRONIC's Spinal and Biologics division to reach unreasonable sales targets.

233. As demonstrated, by years 2006-07, off-label uses accounted for an astounding 85% of INFUSE™ sales; a fact known or recklessly disregarded by all employees, who reviewed marketing data and analyses to set sales quotas for INFUSE™. Indeed, sales quotas for INFUSE™ required sales to grow 20% year-over-year, and MEDTRONIC knew that such increases could not be achieved without substantial off-label sales, and thus that such aggressive targets would encourage off-label promotion by its employees and representatives.

e) MEDTRONIC's Payments to Opinion Leaders.

i) Generally.

234. In addition to encouraging its sales representatives to promote off-label use of INFUSE™, MEDTRONIC also promoted the off-label use of the product through its outside physician "Opinion Leaders" to whom MEDTRONIC paid undisclosed sums in return for publishing medical journal articles and delivering presentations explaining, endorsing, and promoting off-label applications of the product. Indeed, even after settlement with the DOJ and

entry into the CIA as a result of this very activity, MEDTRONIC continued its practice of providing lucrative consulting fees (amounting to millions of dollars per year) to surgeons who actively promoted off-label use of INFUSE™, often with direct involvement by MEDTRONIC's senior management.

235. MEDTRONIC has sought to expand the off-label uses (and has succeeded in doing so) by paying large amounts of money to key "Opinion Leader" spine surgeons around the country, many of whom then published studies and articles advocating the off-label use of INFUSE™ and minimizing the risks or dangers to patients from these uses.

236. Medical device companies look for surgeons who are known as "Opinion Leaders" and who will not only use a high volume of their products, but who can and will persuade other surgeons to use a particular device. Opinion leaders are physicians whose opinions on medical procedures and medical devices are held in high regard by other surgeons. If these influential physicians are willing to promote the use of a certain device, then other surgeons are likely to follow suit and use that device, sometimes including off-label uses which are illegal for the company itself to promote.

237. Many medical device companies, including MEDTRONIC, cultivate relationships with these "Opinion Leaders," paying them handsome (and in the case of INFUSE™, sometimes seven-figure) consulting fees, travel expenses for seminars, sham or exaggerated royalty payments, and numerous other perks, to encourage these physicians to promote the use of a particular medical device.

238. Prior to the date of Plaintiff's spine surgery which involved off-label INFUSE™, MEDTRONIC provided millions of dollars in undisclosed payments to certain spine surgeon "Opinion Leaders" who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements to promote off-label applications of INFUSE™ in the spine. In turn, MEDTRONIC's sales force would direct other physicians to these "Opinion Leaders" or to their written work to further drive off-label

sales of the INFUSE™. In this way, MEDTRONIC consciously and deliberately orchestrated a campaign to end-run the FDA's 2002 approval of and labeling for the INFUSE™ device.

239. MEDTRONIC, for example, paid more than $45 million to the 12 spine surgeons who authored the first 13 studies sponsored by MEDTRONIC on INFUSE™. Additionally, "Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty, and other miscellaneous arrangements." *Staff Report on Medtronic's Influence on INFUSE™ Clinical Studies*, U.S. Senate Committee on Finance, October 25, 2012.

ii) Walter Reed "Opinion Leaders:" Timothy Kuklo, M.D., Rick Sasso, M.D., and David Polly, M.D.

240. Just one of MEDTRONIC's highly compensated "consultants"—Dr. Timothy Kuklo, a former Army physician who retired from the military as chief of orthopaedic surgery at Walter Reed Army Medical Center ("Walter Reed"), the nation's premier military research hospital in December 2006—received hundreds of thousands of dollars per year in fees in the years following the DOJ settlement. Specifically, *The Wall Street Journal* and *New York Times* reported in 2009 that Dr. Kuklo received $356,242 in 2007, $249,772 in 2008 and $132,453 in the first few months of 2009 from MEDTRONIC for consulting, speaking, travel, and training services. MEDTRONIC paid Dr. Kuklo $42,627 in 2006 while he was still on active duty at Walter Reed, as well as amounts totaling $42,295 from 2001 through 2005, primarily for travel to medical conferences and speeches at MEDTRONIC events, including direct payments to hotels and airlines. MEDTRONIC confirmed that Dr. Kuklo was a paid consultant for MEDTRONIC and that the company has paid him more than $800,000 over an eight year period.

241. While it is not inherently illegal or unethical for physicians to perform paid consulting work for medical device companies, the history of the growing INFUSE™ scandal demonstrates an egregious pattern of both MEDTRONIC and its "Opinion Leaders" overstepping ethical lines while recklessly promoting dangerous off-label uses of this product. Dr. Kuklo, for example, worked closely with MEDTRONIC as an active promoter of off-label

uses of INFUSE™; that is, until a U.S. Army investigation into a falsified study touting the benefits of INFUSE™ uncovered shocking misconduct by this former Army surgeon. For example, Dr. Kuklo appeared as a "distinguished guest surgeon" at a MEDTRONIC Spine Division Business Overview Conference Call on September 28, 2006, alongside another MEDTRONIC consultant, Dr. Rick Sasso—who received $150,000 in consulting fees in 2006—as well as Ellis and Peter Wehrly ("Wehrly"), MEDTRONIC Spinal Division Senior Vice President. During the call, a Merrill Lynch analyst asked about "issues that have come up in the past in terms of potential side effects with using INFUSE™ in the cervical region," and whether such off-label use was a concern for surgeons. Dr. Sasso responded by referring to a "Level 1, controlled randomized study which was published in 2002" which, according to Dr. Sasso, demonstrated that "when you used the appropriate dosage of INFUSE™, you did not get problems with esophageal obstruction and problems swallowing." For his part, Dr. Kuklo responded that the question "was well answered as far as appropriate dosage. I think it's really the bottom line."

242. Although Dr. Kuklo's and Dr. Sasso's rendition of the medical literature may not have been entirely accurate—in fact they baldly misrepresented the seriousness of the adverse events that MEDTRONIC knew were occurring in the cervical spine—their misrepresentations only hinted at the influence of MEDTRONIC's payments on its consultants' medical judgment. Indeed, an Army investigation later revealed that Dr. Kuklo deliberately falsified data by exaggerating the benefits of off-label use of INFUSE™ in a study published in the August 2008 issue of *The Journal of Bone and Joint Surgery*.

243. Dr. Kuklo's "study," which purported to compare fusion results of sixty-seven (67) patients who received an autogenous bone graft versus sixty-two (62) that were treated with INFUSE™ to treat certain tibial (shin bone) fractures in injured soldiers (including certain off-label uses), reported that employing INFUSE™ resulted in "strikingly" better outcomes than a traditional (autogenous) bone graft. Specifically, Dr. Kuklo reported that those receiving

autogenous bone grafts had successful fusions in 76% of procedures, while the union rate for the INFUSE™ group was significantly better at 92%; a claimed "striking finding."

244. According to Dr. Kuklo, not only were the reported union rates claimed better with INFUSE™ than with an autograft, but, according to this (falsified) study, patients who received INFUSE™ also reportedly experienced favorable outcomes in other clinical measures. Specifically, the study concluded that "the primary outcome measures of union, rate of infection, and reoperation were all improved with rhBMP-2," and that those treated with INFUSE™ had a "strikingly lower infection rate (3.2%), which we believe is directly attributable to rhBMP-2."

245. MEDTRONIC continued paying Dr. Kuklo as a consultant even after his article was discovered to be largely fabricated and thus retracted by *The Journal of Bone and Joint Surgery*. Indeed, MEDTRONIC only placed Dr. Kuklo on "inactive status" after reports that he had falsified the study's data were published in *The New York Times*.

246. On May 13, 2009, *The New York Times* reported that the U.S. Army's investigation into a study authored by Dr. Kuklo concluded that he falsified an entire study touting the benefits of INFUSE™ to treat wounded soldiers injured in Iraq – conduct that Col. J. Edwin Atwood, an Army physician who led the Army's inquiry, described as "the ultimate tragedy and catastrophe in academic medicine."

247. Per *The New York Times* and *The Wall Street Journal*, the true facts regarding Dr. Kuklo's study were only uncovered when one of the study's supposed "co-authors," Lt. Col. Romney C. Andersen, was congratulated on its publication by a colleague. After this discovery, Lt. Col. Andersen alerted Army investigators who found that:

a. Dr. Kuklo listed four other Army surgeons as "co-authors" without their knowledge, and these four physicians did not participate in or review the article's preparation or submission for publication;

b. The signatures of the four physicians listed as co-authors on the copyright release forms submitted to *The Journal of Bone and Joint Surgery* were forged by Dr. Kuklo;

c. The number of cases cited by Dr. Kuklo in the article differed from the number of cases contained in the U.S. Army's wartime casualty database, with no explanation for the discrepancies in the article;

d. Contrary to Army policy, Dr. Kuklo did not obtain publication review or clearance from Walter Reed prior to submitting the article for publication; and

e. The published results of the article suggested a much higher efficacy rate for INFUSE™ than is supported by the experience of the purported co- authors.

248. According to one of the Army's investigators, Col. Norvell V. Coots, the study cited higher numbers of patients and injuries than the hospital could account for having as patients. According to Col. Coots, "It's like a ghost population that were reported in the article as having been treated that we have no record of ever having existed … this really was all falsified information."

249. After receiving correspondence from Walter Reed dated November 6, 2008 stating that Dr. Kuklo did not follow Army regulations in submitting the article, that the signatures of the purported co-authors had been forged, and that the article's purported co-authors had questioned the study's findings, *The Journal of Bone and Joint Surgery* formally retracted the article and banned Dr. Kuklo from submitting further papers to *The Journal of Bone and Joint Surgery*. As noted in a May 19, 2009 follow-up article in *The New York Times*, when questioned about its ties to Dr. Kuklo, MEDTRONIC repeatedly declined to disclose when it began its financial relationship with him or the extent of funding it provided.

250. As discussed in more detail *supra*, U.S. Senator Charles Grassley discovered that Dr. Kuklo's name did not appear on a list of paid consultants for INFUSE™ provided by MEDTRONIC that the Senator had requested in a September 30, 2008 letter to MEDTRONIC. Senator Grassley disclosed the list MEDTRONIC provided—which included twenty-two (22) physicians who were paid a total of $943,000 from 2005 to 2008—in a May 18, 2009 letter to MEDTRONIC that was published in the Congressional Record the following day. According to the May 18, 2009 letter, Senator Grassley was "concerned" that MEDTRONIC did not provide

Dr. Kuklo's name in response to his inquiry that specifically requested information regarding consultants who work on INFUSE™, as it was "clear that Dr. Kuklo had some sort of consulting agreement" and was named in *The New York Times* as a consultant on INFUSE™. Indeed, by this time, Dr. Kuklo had given countless presentations on behalf of MEDTRONIC about off-label use of the product.

251. The list provided to Senator Grassley also omitted names of other MEDTRONIC consultants who had promoted off-label uses of INFUSE™, such as David Polly, M.D., another former Walter Reed surgeon. Frustrated with MEDTRONIC's omissions, Senator Grassley stated that "[i]n the future, I hope that instead of not providing me with the name of the physician involved in INFUSE™, or any other matter that I am looking into, that MEDTRONIC contact me to avoid the situation in which we find ourselves." A May 19, 2009 *New York Times* article reported that MEDTRONIC also faced a DOJ inquiry regarding its illegal promotion of INFUSE™.

252. As a result, on June 18, 2009, MEDTRONIC disclosed to *The Wall Street Journal* that Dr. Kuklo had received almost $850,000 in payments from MEDTRONIC over the past 10 years, the majority of which—nearly $800,000— were made in the preceding three years when Dr. Kuklo was submitting his bogus fabricated study on INFUSE™ to medical journals for publication. Specifically, MEDTRONIC paid Dr. Kuklo $356,242 in 2007, the year Dr. Kuklo sought publication of the study in two medical journals, and $249,772 in 2008, the year the study was published in the *Journal of Bone and Joint Surgery*. MEDTRONIC made both of these payments after MEDTRONIC announced the settlement with the DOJ in July 2006.

253. In July 2009, Senator Grassley also publicly disclosed information demonstrating that Dr. Kuklo hid his financial relationship from Washington University and failed to disclose his financial ties in conflict-of-interest disclosure forms while he was conducting research related to INFUSE™. In fact, MEDTRONIC financed two separate, unpublished studies that also examined the use of INFUSE™ on Walter Reed patients with combat-related leg injuries while Dr. Kuklo was supposedly conducting research for the falsified study. At the time Washington

University approved the study protocols, Dr. Kuklo indicated on disclosure forms that he did not receive any payments from MEDTRONIC when, in fact, Dr. Kuklo signed a contract with MEDTRONIC shortly after joining the Washington University faculty and had received payments from MEDTRONIC for almost a year into his research.

254. In mid-2007, after Dr. Kuklo disclosed to Washington University that he had received funding from MEDTRONIC, the University's internal disclosure review board re-reviewed Dr. Kuklo's involvement in the MEDTRONIC-sponsored studies and informed him he would have to reduce his personal financial interest with MEDTRONIC to less than $10,000 per year or discontinue his involvement with the research. Dr. Kuklo opted to stop the two studies, which were closed in February 2008.

255. Another highly compensated MEDTRONIC consultant involved in the promotion of off-label INFUSE™ use, Dr. Polly, a professor and Chief of the Spine Service at the University of Minnesota, Department of Orthopaedic Surgery, received consulting fees from MEDTRONIC totaling $1.14 million from 2003 to 2007. As with Dr. Kuklo, MEDTRONIC's financial relationship with Dr. Polly began while the surgeon was on active military duty at Walter Reed. Although Dr. Polly has claimed that his consulting relationship with MEDTRONIC did not begin until 2004, documents obtained through requests under the Freedom of Information Act ("FOIA") reveal that MEDTRONIC paid almost $30,000 in travel expenses for Dr. Polly to speak at various medical conferences in the Bahamas, San Diego, and a $10,000 trip to Switzerland, while he was stationed at Walter Reed in 2003. Dr. Polly attended these conferences to report on his research that purportedly demonstrated that INFUSE™ was more cost effective than traditional spinal fusion procedures.

256. After his discharge from the military, Dr. Polly authored an article with Dr. Kuklo reporting positive results in treating wounded soldiers with rhBMP-2 at Walter Reed. According to their article, published in the November 2004 issue of "Minnesota Medicine," rhBMP-2 was used in more than 100 military patients with traumatic bone fractures who had served in Iraq and Afghanistan. Although the use of INFUSE™ in tibial fractures was not approved until April 30,

2004, Dr. Polly reported that the "decision to use rhBMP-2 was made early in the Afghanistan conflict and was based on evidence from clinical trials in Europe on open tibial fractures that suggested use of rhBMP-2 not only improved bone healing but led to a decreased number of secondary interventions and lower rates of infection." According to Dr. Polly, "the military's experience with rhBMP-2 has been favorable."

257. Moreover, additional evidence demonstrates that, even before his and Dr. Polly's November 2004 article was published, MEDTRONIC reimbursed Dr. Kuklo for a meeting with MEDTRONIC representatives in Memphis, Tennessee on April 20, 2004 regarding "Review of BMP Trauma and Spine Surgery."

258. Dr. Polly later sought a government grant for a similar study in May 2006, when he testified before the Defense Subcommittee of the U.S. Senate Appropriations Committee regarding research that would examine the use of INFUSE™ and antibiotics to treat traumatic and infected bone fractures. Dr. Polly stated that he was "speaking on behalf of the American Academy of Orthopedic Surgeons." However, according to information recently released by Senator Grassley, who, in conjunction with Senator Baucus, has been conducting an inquiry into MEDTRONIC's consulting payments, Dr. Polly actually billed MEDTRONIC $7,000 in connection with his Senate testimony, and was therefore speaking on behalf of MEDTRONIC, not the American Academy of Orthopedic Surgeons, as he had claimed. Furthermore, Dr. Polly billed MEDTRONIC a total of $50,000 over several months for his lobbying efforts in securing the $466,644 Department of Defense grant for this INFUSE™ research study.

259. The information released by Senator Grassley, discussed more fully *supra*, which includes billing reports submitted to MEDTRONIC by Dr. Polly and approved by MEDTRONIC, indicates that throughout this period, Dr. Polly had frequent meetings, telephone calls, and email correspondence with numerous MEDTRONIC senior executives, including former COO Michael DeMane ("DeMane"), and former President of MEDTRONIC Spinal and Biologics Wehrly, while speaking frequently regarding INFUSE™ at medical conferences and other events. For example, the records show meetings and other contacts between Dr. Polly and

Hawkins on the following dates: February 13, 2007; June 15, 2007; July 27, 2007; August 8, 2007; August 24, 2007; September 26, 2007; and September 27, 2007. Indeed, they further show that Dr. Polly billed MEDTRONIC for a meeting with Hawkins on July 13, 2005 to discuss a "spine surgery advocacy effort."

iii) Opinion Leader Dr. Thomas A. Zdeblick.

260. Thomas A. Zdeblick, M.D., the Chairman of the Department of Orthopedics and Rehabilitation at the University of Wisconsin, received over $19 million from MEDTRONIC from 2003 to 2007 for consulting services and royalty payments. Although Dr. Zdeblick only disclosed annual payments exceeding $20,000 in University conflict of interest forms, he actually received between $2.6 and $4.6 million per year. In 2007 alone, Dr. Zdeblick received $2,641,000 in consulting fees from MEDTRONIC. From 1998 through 2004, Dr. Zdeblick was paid an annual salary of $400,000 by MEDTRONIC under a contract that only required him to work eight days per year at a MEDTRONIC site in Memphis, Tennessee, and to participate in "workshops" for surgeons.

261. Dr. Zdeblick also has been a significant contributor to MEDTRONIC's promotion of INFUSE™, authoring seven peer-reviewed articles on rhBMP-2 and appearing as a presenter at medical conferences and symposia in which the topics included discussion of off-label uses of the product. On a MEDTRONIC-owned website, "www.Back.com," Dr. Zdeblick describes the advantages of INFUSE™ and appears in an online video discussing the benefits of the product.

262. As discussed more fully *supra*, on January 16, 2009, *The Wall Street Journal* reported on a letter sent by Senator Charles Grassley to Kevin P. Reilly, President at the University of Wisconsin, regarding Defendants' consulting and royalty payments to Dr. Zdeblick, who co-authored preliminary studies that led to the FDA's approval of INFUSE™. Although the University is required to monitor its researchers' financial conflicts-of-interest, the amounts MEDTRONIC paid Dr. Zdeblick far exceeded those he reported to the University. Specifically, Dr. Zdeblick was required to disclose annual amounts in excess of $20,000 per year, and in one year reported payments in excess of $40,000. In reality, Dr. Zdeblick received

between $2.6 million and $4.6 million per year from MEDTRONIC, totaling an astonishing $19 million in payments, from 2003 through 2007.

263. As revealed in a June 20, 2009 article in the *Milwaukee Journal Sentinel*, Dr. Paul A. Anderson, an orthopedic surgeon and colleague of Dr. Zdeblick at the University of Wisconsin School of Medicine and Public Health, was paid $150,000 by MEDTRONIC for just eight days of work. Dr. Anderson, along with MEDTRONIC consultants Drs. Boden, Keith H. Bridwell, and Jeffrey C. Wang, authored a July 2007 article in *Journal of Bone and Joint Surgery* article, titled "What's New in Spine Surgery." The article discussed, among other things, a study that examined the use of INFUSE™ in an off- label Posterolateral Fusion procedure. According to the authors, the study reported that INFUSE™ improved fusion rates when used in combination with iliac crest bone graft in a procedure in which the BMP was wrapped around local bone as a bulking agent. According to the authors, the study's findings suggested that "the current [INFUSE™] kit, while likely not sufficient as a stand-alone graft substitute for the posterolateral spine, can provide a significant enhancer effect, improving the success of an autogenous bone graft."

264. On June 20, 2009, the *Milwaukee Journal Sentinel* reported that, during calendar year 2008, MEDTRONIC paid Dr. Zdeblick $2 million in royalty payments for eight days of consulting work, and that Dr. Paul Anderson received $150,000 in MEDTRONIC consulting fees for working just eight days.

iv) Norton Hospital Leatherman Spine Center Opinion Leaders.

265. Another set of highly compensated surgeons, those affiliated with the Norton Hospital Leatherman Spine Center in Louisville, Kentucky, collectively received more than one million dollars in consulting fees in 2006 alone, including Drs. John R. Johnson ($162,750), Steven D. Glassman ($200,300), Rolando M. Puno ($106,000), John R. Dimar, II ($192,300), David Rouben ($109,300), Mitch Campbell ($212,000) and Mladen Djurasovic ($55,900).

266. According to CW 1, several surgeons from the Leatherman Spine Center were requested by MEDTRONIC to speak at MEDTRONIC-sponsored physician talks attended by

between ten and twenty-five surgeons, including several "pretty high profile" physicians. At these physician talks, a MEDTRONIC consultant, such as one of the surgeons at the Leatherman Spine Center, provided presentations covering the purported benefits of off-label usage of INFUSE™. According to CW 1, "What [MEDTRONIC] would do is bring in one of their 'paid consultants' and set up a dinner in the area and invited a number of physicians to attend." The guest surgeon—the "paid consultant"— would then "basically give a presentation on off-label usage." Importantly, these physician talks were also attended by all MEDTRONIC sales representatives who worked in the area.

267. These same MEDTRONIC-funded surgeons associated with the Leatherman Spine Center have also written extensively on off-label uses of INFUSE™. These surgeons have collectively authored at least 15 articles addressing the use of BMP, including many of the early medical articles on the use of INFUSE™ in off-label posterolateral lumbar and anterior cervical fusion procedures. Specifically, Dr. Campbell has contributed to at least eight articles examining the use of BMP; Dr. Dimar has authored nine; Dr. Djurasovic, four; Dr. Johnson, five; Dr. Puno, five; and Dr. Glassman has written at least fifteen articles addressing the use of BMP, the vast majority of which involve applications of the product in off-label procedures.

v) **Other Various Opinion Leaders.**

268. Several physicians who authored a May 2003 article describing positive results of INFUSE™ used in the cervical spine were paid tens of thousands of dollars in consulting fees by MEDTRONIC. The article, "New Technologies in Anterior Cervical Spine Fixation," published on Spine Universe, a website intended for the general public that provides information regarding spinal disorders and treatment, described the physicians' use of INFUSE™ "in the cervical spine with very good results." According to the authors, "[p]reliminary results are promising and INFUSE™ may be especially appropriate in people undergoing multiple level fusions" (emphasis added)—i.e., for indications outside FDA limited approval to single-level fusion procedures.

269. One of the authors of this article, Dr. Regis Haid, Jr., received consulting fees of $50,000 from MEDTRONIC in 2006 and similar amounts in the previous two years. Another author, Dr. Gerald Rodts, received payments of $80,000 from MEDTRONIC in 2006 and similar amounts in the previous two years. The Spine Universe article does not mention that its authors received compensation from MEDTRONIC, nor do the website profiles of Dr. Haid and Dr. Rodts, both of whom serve on the publication's editorial board, disclose their financial ties to MEDTRONIC.

270. Dr. Haid was also the lead author of an article describing the results of the study of INFUSE™ in off-label PLIF procedures that was halted in December 1999 after several patients experienced adverse incidents of uncontrolled bony overgrowth. In addition, two of the article's other authors—Dr. J. Kenneth Burkus and Dr. Charles L. Branch—received consulting fees from MEDTRONIC. Specifically, MEDTRONIC paid Dr. Branch $154,900 in 2006 and similar amounts in the preceding two years, while Dr. Kenneth Burkus—who has written over a dozen articles addressing the use of rhBMP-2, including studies examining the use of INFUSE™ in off- label PLIF and anterior cervical procedures—received $416,775 in 2006 and similar amounts in the two preceding years.

271. Although the negative outcomes in the PLIF study prompted the FDA Advisory Panel to recommend a more restrictive labeling and indication in approving INFUSE™, the MEDTRONIC-funded authors reviewing the study's results surprisingly did not find the incidents of bony overgrowth to be a clinically significant concern. Shockingly, the physicians noted, "[a]lthough not desirable, bone formation in the spinal canal does not appear to have a discernible effect on patient outcomes," and "the de novo rhBMP-formed bone occurred predictably, not compressing the neural structures."

272. In a commentary on the study, Dr. Neil Kahanovitz, an independent surgeon, questioned the authors' interpretations, suggesting that they may have been "overwhelmed by their enthusiasm of using" rhBMP-2 in a PLIF procedure. Dr. Kahanovitz noted that, while there are "lengthy discussions of various trends throughout this study, which imply the superiority of

rhBMP over autograft . . . one fact remains: in every clinical measure examined in this study, there were no statistically superior outcomes in the rhBMP group except one, and the clinical significance of this one statistically significant finding is unclear."

273. Importantly, Dr. Kahanovitz also disagreed with the authors' conclusion that the presence of bone growth in the spinal canal and foramina (the two apertures between vertebrae) in those patients who received rhBMP-2 had no clinical implications. Rather, Dr. Kahanovitz predicted that "most surgeons would be less than enthusiastic to see this statistically significant variable present in the majority of their patients."

274. CW 1 stated that Drs. Lawrence "Larry" G. Lenke and Keith H. Bridwell, two surgeons from Washington University in St. Louis – where Dr. Kuklo worked as an associate professor until recently – similarly acted as "Opinion Leaders" or "guest surgeons" during "corporate visits" in which MEDTRONIC would invite targeted surgeons to attend training sessions in Memphis, Tennessee. While in Memphis, the visiting surgeons met with MEDTRONIC corporate officers, product managers, and guest surgeons, such as Drs. Lenke and Bridwell. The visiting surgeons also received "hands-on training" on INFUSE™, including instruction in cadaver labs. According to CW1, who personally attended two such meetings, "[t]here was training on off- label procedures, for sure." The visiting surgeons "would bring up the use of INFUSE™ and ask how to use it, and [the guest surgeons] would show them how to do it." CW1 stated that MEDTRONIC chose which surgeons to invite to these corporate visits based, in part, upon the volume of INFUSE™ procedures they performed.

275. Another prominent MEDTRONIC consultant, Jeffrey Wang, M.D., the Chief of Spine Surgery for the Department of Orthopaedic Surgery and Executive Co-Director of the University of California, Los Angeles's ("UCLA") Comprehensive Spine Center, also spoke about off-label uses of INFUSE™. Unsurprisingly, Senator Grassley recently discovered that Dr. Wang received $275,000 in royalty and consulting payments from MEDTRONIC from 2003 until 2008.

276. Furthermore, Dr. Wang failed to disclose his substantial financial relationship with MEDTRONIC while researching MEDTRONIC products, which violated UCLA's policy requiring him to do so. For example, on a disclosure form to UCLA dated January 10, 2007, Dr. Wang checked "no" when asked if he received income of $500 or more from MEDTRONIC, notwithstanding the fact that MEDTRONIC was, at that very moment, funding one of Dr. Wang's studies. In fact, Dr. Wang received $14,600 on January 4, 2007 for "lecture and teachings at spine meetings and universities in Korea for one week." As a result of his repeated failures to disclose payments received from MEDTRONIC, Dr. Wang lost his position as Executive Co-Director of UCLA's Comprehensive Spine Center.

277. As discussed more fully *supra*, Senator Grassley also discovered that, in addition to the compensation to MEDTRONIC consultants, MEDTRONIC collectively paid twenty-two other surgeons $943,000 from 2003 to 2008 to work on matters specific to INFUSE™.

278. In June 2011, one of the leading journals on spine surgery, *The Spine Journal*, described more fully *supra*, devoted an entire issue to publishing various articles regarding the risks associated with INFUSE™, including articles on MEDTRONIC's failure to accurately report the side effects from its clinical trials; MEDTRONIC's failure to report that many of the authors who studied and promoted INFUSE™ had significant financial ties to MEDTRONIC, with a median range of $12 to $16 million per study; that INFUSE™ can cause severe injuries to the spinal nerves and spinal cord; that off-label use of INFUSE™ can lead to other severe side effects; and that MEDTRONIC and its paid consultants/study authors downplayed the risks associated with INFUSE™, over-emphasized its benefits and over-emphasized the risks associated with traditional non-INFUSE™ spine fusion procedures.

vi) MEDTRONIC MANAGERS AND DR. MICHELSON

279. Defendant Medtronic Managers, in collaboration with other Defendants, and in furtherance of a business plan of Medtronic, intentionally and/or recklessly engage in vigorous and unlawful overpromotion of the off-label use of Infuse in California, and other states, through the use of consultants, sales representatives, key opinion leaders and other agents of Defendant

Medtronic, for the purpose of misleading physicians, including, but not limited to the surgeons providing care to Plaintiff.

280. Critical here is that Defendant Medtronic Managers did, upon information and belief, pay certain orthopedic surgeons in California, including, but not limited to Drs. Jeffrey E. Deckey, David Lee Skaggs, Todd Lanman, Theodore G. Obenchain, and certain physicians at the San Francisco Spine Institute, sums of money, in excess of $250,000.00, for services these healthcare providers did not render, in order to obtain testimonials and support for the off-label use of Infuse.

281. Each Defendant Medtronic Managers' activities did, in part, cause the introduction into the stream of commerce, the INFUSE product received by Plaintiffs.

282. Plaintiffs are informed and believe, and thereon allege, that Dr. Michelson substantially contributed to the development of the technology related to Infuse. Medtronic's own website fact sheet for Infuse gives credit to Dr. Michelson, stating that Infuse "Incorporates technology developed by Gary K. Michelson, M.D.," thus, Dr. Michelson's name was directly tied in with the Infuse on Medtronic's websites. Dr. Michelson's has numerous patents which involved the use of cages and spinal fusion implants, which are the core of Medtronic's business.

f) U.S. Senators' Letters to MEDTRONIC Regarding to the Promotion and Marketing of INFUSE™.

i) September 30, 2008 Letter.

283. Despite the July 2006 Settlement with the DOJ, concerns regarding MEDTRONIC's off-label marketing activities and related payments to doctors continued.

284. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to MEDTRONIC noting that earlier in 2008, MEDTRONIC's outside counsel provided to the Special Committee on Aging a written account of MEDTRONIC's efforts to comply with the July 2006 Settlement Agreement it reached with the DOJ concerning allegations that MEDTRONIC and its subsidiary improperly compensated surgeons and physicians in connection with the INFUSE™ device.

285. Senator Kohl's letter expressed several concerns, including the following:

> That account also addressed the corporate integrity agreement (CIA) that MEDTRONIC and its subsidiary entered into with the Office of the Inspector General of the United States Department of Health and Human Services stemming from those same allegations. In that same letter to the Committee, MEDTRONIC and its subsidiary both denied that "improper payments were made to physicians in the first place (MEDTRONIC's agreement with DOJ does not contain any admission of liability), much less that improper payments 'have continued.' Consequently, it was with concern that I read recent articles, in the *Wall Street Journal* and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by MEDTRONIC to surgeons and physicians.
>
> These continuing allegations are directly relevant to the Committee's oversight of inappropriate physician compensation practices within the medical device industry. All of the major orthopedic device companies that settled with DOJ over such allegations were required to publicly reveal information related to their payments to physicians. MEDTRONIC's response to the Committee's initial inquiry articulated no specific reasons as to why MEDTRONIC has yet to voluntarily make the same disclosures.

286. In this letter, Senator Kohl requested both documentation of MEDTRONIC's efforts to comply with the July 2006 Settlement Agreement and interviews with corporate witnesses and documents "given the ongoing, serious concerns publicly raised regarding the integrity and transparency of MEDTRONIC's physician compensation practices."

287. Senator Kohl also asked MEDTRONIC to explain "the circumstances that led MEDTRONIC's former counsel to file suit against the company [alleging improper payments to physicians] and how that matter was subsequently settled."

288. Also on September 30, 2008, U.S. Senator Charles Grassley sent a similar letter to MEDTRONIC pertaining to the marketing of INFUSE™ and allegations of related kickbacks to physicians regarding the sale of INFUSE™, noting that:

> Last week, the *Wall Street Journal (WSJ)* reported on allegations of financial perks provided to doctors that included "entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in."[15] I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and

[15] David Armstrong, "Lawsuit Says MEDTRONIC Gave Doctors Array of Perks," *Wall St. J.*, Sept. 25, 2008.

questions.

289. Senator Grassley went on to express his concern over the *Wall Street Journal*'s reports "that one of the incentives MEDTRONIC provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

290. This letter specifically addressed issues related to MEDTRONIC's marketing of INFUSE™:

> Fourth, earlier this month the WSJ reported on problems with off-label use of MEDTRONIC's INFUSE™. INFUSE™ is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that MEDTRONIC gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of INFUSE™. The allegations that MEDTRONIC has been disguising these consulting agreements as inducements or kickbacks for physicians to use INFUSE™ are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what if anything has changed since these reported events.

291. Senator Grassley, in his September 30, 2008 letter, also questioned why several lawsuits against MEDTRONIC pertaining to INFUSE™ remained under seal, and indicated that he would like to "better understand the status of these lawsuits and the procedural process that has led to the current situation."

ii) June 21, 2011 Letter.

292. The U.S. Senate Committee on Finance investigated whether MEDTRONIC has continued to misrepresent the adverse events that result from INFUSE™ and rhBMP-2, as well as the possibility that MEDTRONIC improperly influenced clinical trials and reporting regarding rhBMP-2.

293. On June 21, 2011, U.S. Senators Charles Grassley and Max Baucus sent another letter to MEDTRONIC on behalf of the Senate Committee on Finance requesting that MEDTRONIC produce documents and communications pertaining to "adverse postoperative events and/or medical complications" resulting from the use of rhBMP-2.[16] The letter also

[16] Letter from Grassley and Baucus (June 21, 2011), *available at*, http://finance.senate.gov/newsroom/chairman/release.

requests that MEDTRONIC provide "[a] detailed account of payments that MEDTRONIC made to all INFUSE™ clinical investigators."

294. In their June 21, 2011 letter, Senators Grassley and Baucus state: "We are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of INFUSE™ on behalf of MEDTRONIC were aware that INFUSE™, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to MEDTRONIC."

295. The letter further states: "We are also concerned that other severe side-effects of INFUSE™ and similar bone-growth products developed by MEDTRONIC may have been unreported or under-reported in clinical literature. Reports have linked INFUSE™ to potentially fatal swelling in the neck and throat, and radiating leg pain. Concerns have also been expressed about a potential link to cancer."

iii) December 13, 2011 Letter.

296. Senators Herb Kohl, Charles Grassley, and Richard Blumenthal wrote to MEDTRONIC again in December 2011 demanding more information from the company over adverse events caused by on-label and off-label use of INFUSE™. The letter noted that "your company has experienced safety issues, such as with your spine product INFUSE™."

297. The letter also demanded that MEDTRONIC explain whether or not it requires physicians who receive funds from MEDTRONIC to disclose those payments to their patients before the patients receive one of MEDTRONIC's medical devices and "If not, why not?"

298. This new letter requires that MEDTRONIC produce this information to the U.S. Senate's Special Committee on Aging by no later than January 23, 2012.

299. On information and belief, this continued investigation by a U.S. Senate committee suggests that MEDTRONIC has not changed its ways with regard to its illegal promotion of INFUSE™, despite signing the CIA and paying a $40 million fine to DOJ in 2006.

g) **June 2011 Issue of *The Spine Journal.***

300. In June 2011, the *Spine Journal*, a leading medical journal in the United States, published a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of rhBMP-2 (INFUSE™) in the spine.

301. This special edition reviewed thirteen peer-reviewed articles about rhBMP-2 by MEDTRONIC-sponsored authors, and concluded that these articles had inaccurately reported the safety of rhBMP-2 applications in the spine by underestimating its risks.

302. In an editorial summarizing the findings of this special issue, five prominent physicians, including spine surgeons at Stanford University Medical Center, wrote that the earlier industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2-related clinical adverse events." For example, the industry-sponsored articles omitted mention of indications from the earliest trials of inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of sterility and cancer risks associated with rhBMP-2, as reported in FDA documents and hearings. The trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review/publication shortfalls.

303. According to this editorial and several of the accompanying articles in the *Spine Journal*, the thirteen MEDTRONIC-funded articles reported only successful fusions and extremely low or nonexistent rates of complications with INFUSE™, which led to the growth of "off-label" use of INFUSE™ in lumbar fusion procedures. The articles "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths."

304. Contrary to the conclusions of the earlier MEDTRONIC-sponsored trials and articles, an article in this special issue of the *Spine Journal* suggested "an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach."

> Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early

> postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. *Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.* In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy."

Eugene J. Carragee, Eric L. Hurwitz & Bradley K. Weiner, *A Critical Review Of Recombinant Human Bone Morphogenetic Protein-2 Trials In Spinal Surgery: Emerging Safety Concerns And Lessons Learned, The Spine Journal* 11, 471-72 (2011) (emphasis added).

305. This article also reported that ten of the earlier industry-sponsored rhBMP-2 trials were funded in whole or in part by the manufacturer of rhBMP-2 (INFUSE™), MEDTRONIC. Furthermore, in twelve of these earlier studies, the median-known financial association between the authors and MEDTRONIC Inc. was approximately $12,000,000-$16,000,000 per study (range, $560,000-$23,500,000). *Id.* at 475.

306. The following are some of the other significant conclusions in these articles in the June 1, 2011 Issue of *The Spine Journal*:

a. Many of the risks now accepted have been known since a publication by Poynton and Lane in 2002, which listed overgrown and uncontrolled bone formation, osteoclast activity (graft subsidence, migration, loss of fixation etc.), local safety (inflammation, edema, wound problems, and infection), potential negative effect of BMPs on exposed dura and nerves (neurologic events, retrograde ejaculation, persistent bladder retention, early back pain, leg pain, radiculitis, functional loss, carcinogenicity). *However, it appears that these risks were ultimately washed out and marginalized by the wealth of positive data from industry-sponsored studies.*

b. A 2-year rhBMP-2 follow-up published by Burkus, et al., reported no adverse events. However, in a 6-year follow-up publication using the same subjects, the

authors contradict their earlier publication stating that there had been seven early adverse events associated with subsidence in the rhBMP-2 group, yet they were not reported in the two year follow-up.

c. In fact, on closer inspection of the Burkus studies, it was noted that all adverse events mentioned in the six-year follow-up had occurred within the first two years.

d. Furthermore, four of the adverse events required further surgery, and 22 additional surgeries for device failures occurred in the same rhBMP-2 group between 0-2 years after surgery according to the FDA summary, but were not specifically reported in the 2003 or 2004 studies, which were the same patients over the same time frame.

e. The estimates of rhBMP-2 safety from the original publications underestimated rhBMP-2-related adverse events of the product. In the small pilot studies, there were inadequate numbers to assess safety, but some suggestion of potential harm was seen in at least one study. In the larger trials, there is evidence in each trial that rhBMP-2 complications may be common and may be serious, but in each publication these were underreported.

f. The presence and magnitude of conflicts-of-interest and the potential for reporting bias were either not reported or were unclear in each of the original industry sponsored studies. Some of the conflicts-of-interest statements reported appeared to be vague, unintelligible, or were internally inconsistent.

g. The original estimates of ICBG (Iliac Crest Bone Graft, the pre-rhBMP-2 gold standard procedure for spinal fusion) harvesting morbidity were based on invalid assumptions and methodology. This in turn may have exaggerated the benefit or underestimated the morbidity of rhBMP-2 in the clinical situations tested.

h. The control group methods and techniques, as selected for both posterior approach methods (PLIF and PLF) were potentially handicapped by significant design bias against the controls.

i. In those studies for which other data sources have been made available on the same patient sets (either FDA documents or subsequent reporting of follow-up data), serious contradictory findings have emerged. Major complications, additional surgeries, neurologic/urologic injury, and major back/leg pain events were apparently observed but not reported in the original articles.

j. By falsely reporting perfect or near perfect safety, the original studies might have led others to widespread off-label use of the product with some potentially catastrophic outcomes. Revised estimates of adverse events are:

i. Posterior lumbar interbody fusion techniques: 25-50% risk of associated adverse events.

ii. Anterior lumbar interbody fusion: 10-15% risk of adverse events.

iii. Anterior cervical fusion: 40% greater risk of adverse events in the acute postoperative period including potentially life-threatening complications.

iv. Posterolateral fusions: equivalent or greater early postoperative risk of morbidity compared with ICBG harvesting for this dosage; 16-20% of rhBMP-2 subjects had adverse back and leg pain events, *a probable two to threefold increase in the first three months after surgery over control groups* (emphasis added).

h) <u>October 25, 2012 U.S. Senate Committee on Finance Report on Medtronic's Manipulation of the INFUSE™ Studies and Close Financial Ties with Researchers</u>

306. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into MEDTRONIC, which revealed questionable ties between the company and its physician "Opinion Leader" consultants tasked with testing and reviewing INFUSE™. Without public disclosure of their roles, MEDTRONIC employees collaborated with the physician authors to edit – and in some cases, write – segments of published studies on INFUSE™. The studies may have inaccurately represented INFUSE™'s risks and may have overemphasized the

side effects of prior more traditional treatments. The Senate report found that MEDTRONIC also maintained significant, previously-undisclosed financial ties with the physicians who authored the early studies on INFUSE™, making $210 million in payments to physicians over a 15-year period.

307. "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has," Senator Baucus said. "Patients everywhere will be better served by a more open, honest system without this kind of collusion."

308. "These findings emphasize the value of the Grassley-Kohl Physician Payments Sunshine Act, which will result in public disclosure of industry payments to physicians starting next year. The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and studies they feature," Grassley said. "These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

309. The report released on October 25, 2012 by Senators Baucus and Grassley on behalf of the U.S. Senate Finance Committee – which has sole jurisdiction over Medicare and Medicaid – was the product of an investigation they began in June 2011.[17] The major findings of the investigation include:

a. MEDTRONIC was involved in drafting, editing, and shaping the content of medical journal articles on INFUSE™ authored by its physician consultants who received significant amounts of money through royalties and consulting fees from MEDTRONIC. The company's significant role in authoring or substantively editing

[17] The Senate's full report is available online at: http://www.finance.senate.gov/newsroom/chairman/download/?id=e54db17c-a475-4948-bd81-69c8740c6aaf. In the interest of brevity, Plaintiff has not attached the full 2,315 page report.

these articles was not disclosed in the published articles. Medical journals should ensure any industry role in drafting articles or contributions to authors be fully disclosed.

b. MEDTRONIC paid a total of approximately $210 million to physician authors of MEDTRONIC-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a MEDTRONIC employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with INFUSE™ in a 2005 *Journal of Bone and Joint Surgery* article.

d. MEDTRONIC officials inserted language into studies that promoted INFUSE™ as a better technique than an alternative by emphasizing the pain associated with the alternative.

i) Further Evidence of MEDTRONIC's Off-label Promotion.

310. MEDTRONIC's knowledge and promotion of off-label use of INFUSE™ is further evidenced by comparing sales of the rhBMP-2 component to the sales of the LT-Cage™ component (both components are required pursuant to FDA approval). On information and belief, MEDTRONIC sells the rhBMP-2 component separately from the LT-Cage™ in order to illegally and improperly promote off-label uses of INFUSE™ in the lumbar spine and in the cervical spine, procedures in which the LT-Cage™ is not used. As a result, sales of the rhBMP-2 component are and were at all relevant times far larger than sales of the LT-Cage™ component, despite FDA requirements that both be used according to the product's labeling; i.e. that the entire medical device (rhBMP-2 and the LT-Cage™) be used in the procedure.

311. As described in detail above and throughout this Complaint, therefore, MEDTRONIC's off-label promotion of INFUSE™ was not truthful. Instead, MEDTRONIC's off-label promotion of INFUSE™ was false and misleading. "Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection." *United States v. Caronia*, No. 09-5006-cr, 2012 U.S. App. LEXIS 24831, at *39, n. 11 (2d Cir. Dec. 3, 2012).

312. MEDTRONIC's aggressive off-label promotion described above created the conditions for widespread acceptance by spine surgeons of the off-label uses of INFUSE™ after the 2002 PMA approval, and MEDTRONIC's violations of federal law described above (which parallel Plaintiff's state-law tort claims) directly caused or significantly contributed to the widespread off-label use of INFUSE™ generally, and also specifically with respect to Plaintiff. In particular, MEDTRONIC's off-label promotion activities and failure to report adverse events caused spine surgeons, including Plaintiff's surgeon to use INFUSE™ in dangerous off-label procedures.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION -- MANUFACTURING DEFECT

(Against All Defendants and Does 1-100)

Plaintiffs repeat and realleges every allegation set forth above as if fully set forth herein.

313. Plaintiffs' use of Infuse off-label in spinal fusion surgery was a reasonably foreseeable use, marketed and promoted by Defendants.

314. Defendants placed Infuse on the market in the ordinary course of business and knew Infuse was to be used without inspection for defects.

315. The Infuse drug implanted into Plaintiffs was defective, as evidenced by its failure to comply with the manufacturing specifications required by Infuse's Premarket Approval and Current Good Manufacturing Practices under the FDCA.

316. The drug was defective when it left Defendant's hands. Upon information and belief, 6Plaintiffs' physicians at all times assembled and inserted the drug in accordance with proper procedure and was received in accordance with normal shipping and storage procedures from the manufacturers. Despite their conformance with procedure, the use of the drug resulted in nerve compression and severe, chronic, ongoing pain. As a result, the drug proximately caused Plaintiffs' injuries and damages in a sum in excess of the jurisdictional minimum of this Court.

SECOND CAUSE OF ACTION
FAILURE TO WARN

(Against All Defendants and Does 1-100)

317. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

318. Plaintiffs allege Defendants had an established duty to warn of the dangers in using Infuse for off-label purposes which makes Infuse unreasonably dangerous to use without such warning. As alleged, Defendants were aware of the dangers generally known to the scientific community at the time they manufactured and distributed Infuse.

319. Defendants failed to provide warning of the dangers of using Infuse off-label, specifically failing to warn Plaintiffs and their treaters regarding known dangers including the danger of spinal immobility and nerve damage occurring, as alleged in Applicable FDA Regulations Paragraph 12(c). Defendants' failure to warn Plaintiffs of the dangers of using Infuse off-label caused themto undergo an implantation of Infuse and proximately caused them to suffer injuries alleged and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

THIRD CAUSE OF ACTION -DESIGN DEFECT

(Against All Defendants and Does 1-100)

320. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

321. Plaintiffs allege that Infuse, when used off-label, was designed in a materially defective manner.

322. Design defect claims for uses of Infuse off-label are not pre-empted by 21 U.S.C. § 360k(a) nor impliedly pre-empted under *Buckman Co v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001), because Defendants actively and illegally promoted and marketed Infuse's off-label use in violation of its Premarket Approval and because there is a right of action for strict liability in defective design of a product separate from the FDCA's causes of action in California.

323. As alleged in Applicable FDA Regulations Paragraphs 10 through 11, Defendants violated the FDCA by introducing and promoting an adulterated product. Accordingly, this allegation "parallels" the FDA regulation in accordance with § 360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

324. Further, the off-label use of Infuse was defective in design based on California's strict liability under its theory of products liability.

325. Plaintiffs allege herein, Infuse was used in an intended or reasonably foreseeable manner. This off-label usage of Infuse was not only reasonably foreseeable, but explicitly intended by the promotion and marketing, by Defendants.

326. Infuse was in a defective condition when it left Defendants' hands. As alleged, Infuse failed, resulting in injury.

327. Infuse caused bone growth in Plaintiffs, leading to additional injuries. Infuse is the proximate cause of Plaintiffs' injuries and damages, as alleged herein and additional and general damages in a sum in excess of the jurisdictional minimum of this Court.

FOURTH CAUSE OF ACTION -- NEGLIGENCE

(Against All Defendants And Does 1-100)

328. Plaintiffs repeat and reallegs every allegation set forth above as if fully set forth herein.

329. A proximate cause of Plaintiffs injuries and damage is the negligence and misrepresentations of Defendants through their agents, sales representatives/consultants, paid Key Opinion Leaders, servants and/or employees acting within the course and scope of their employment, negligently, carelessly and recklessly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing INFUSE, and including among other things:

i. Negligently and carelessly engaging in the illegal off-label promotion of INFUSE by recommending to physicians, including Plaintiffs Physicians, and instructing them to use it in procedures for which it had not been approved;

ii. Negligently, carelessly and recklessly promoting the off-label use of INFUSE by instructing, promoting and directing the use of the product in cervical and lumbar fusion procedures that had not been approved by the FDA;

iii. Negligently, carelessly and recklessly failing to disclose to physicians that the promoted off-label use of INFUSE can result in serious side effects;

iv. Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with the off-label use of INFUSE;

v. Negligently, carelessly and recklessly representing that the off-label use of INFUSE was safe when, in fact, it was unsafe;

vi. Negligently, carelessly and recklessly promoting INFUSE beyond the narrow and limited uses for which it was approved;

vii. Negligently, carelessly and recklessly failing to adequately warn the medical community, the general public, plaintiffs surgeon and plaintiff of the dangers, contra-indications, and side effects from the off-label use of INFUSE;

viii. Negligently, carelessly and recklessly failing to act as a reasonably prudent drug manufacturer.

ix. Commissioning studies which misrepresented the risks associated with off-label use of INFUSE;

x. Compensating the authors of the above studies monetarily for their opinions;

xi. Other violations according to proof.

330. Before Plaintiffs were given INFUSE through an off-label cervical or lumbar fusion procedure, Defendants, based upon the state of knowledge as it existed at the time, knew or should have known that such a use could be dangerous and unsafe, and knew or should have known that such a use could result in severe, chronic, ongoing numbness throughout the body, acute pressure and headaches, and other serious side effects.

331. Failure to comply with the above FDCA and PMA requirements amounted to a breach of the duties owed to Plaintiffs. Such acts also constitute adulteration, misbranding, or both under FDCA, 21 U.S.C. §§321, *et seq.*, and therefore subject Defendants to civil liability for all damages arising therefrom, under the theory of negligence per se.

332. Had Medtronic Defendants complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action.

333. Plaintiff, having had INFUSE implanted into her spine, is within the class of persons that the above-referenced federal statutes and regulations are designed to protect, and their injuries are the type of harm these statutes and regulations are designed to prevent.

334. As a direct and proximate result of the acts and conduct of Defendants, Plaintiff was injured in her health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to their damage in an amount in excess of the jurisdictional minimum of the Court.

335. As a further direct and proximate result of the acts and conduct of the Defendants, Plaintiff has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

336. As a further direct and proximate result of the acts and conduct of Defendants, Plaintiff has incurred medical, hospital and related expenses and, on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

FIFTH CAUSE OF ACTION -- FRAUD

(Against All Defendants And Does 1-10)

337. Plaintiffs repeat, reallege, and incorporate herein by this reference, all of the preceding allegations as though set forth in full.

338. As a pharmaceutical company, Defendants had an affirmative continuing duty to warn the public and medical community regarding risks it knew, learned, or should have known about associated with its medical devices and pharmaceutical products, and had an affirmative, continuing duty to the FDA regarding the same.

339. Had Medtronic Defendants complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action

340. Defendants concealed adverse information and provided inaccurate or misleading information which was material to treating surgeons' treatment decisions, which misled surgeons and patients who were relying on those surgeons' professional judgment, including Plaintiff and her treating surgeon. This misleading information, along with omissions of material facts related to Infuse's safety and effectiveness, caused health care providers, patients and the general public, including Plaintiff and her surgeons, to be misled about Infuse's risks and benefits and deprived surgeons from making a proper risk/benefit assessment as to the use and off-label use of Infuse.

341. Through internal adverse event reports, Defendants knew that the off-label use of Infuse was not effective and could lead to serious side effects, including but not limited, to severe, chronic, and ongoing numbness in the body and acute pressure and headaches, and other serious side effects. Defendants failed to take any measures whatsoever to alert surgeons or the public regarding these risks and instead continued to promote the off-label use of Infuse as safe and effective.

342. Plaintiff is informed and believes and based thereon alleges that, despite knowing that the off-label promotion of Infuse was illegal, Defendants, through its sales representatives/consultants and Key Opinion Leaders, promoted the off-label use of Infuse to

Plaintiff's physicians and concealed that the off-label use of Infuse could result in unwanted bone growth and other serious side effects.

343. Plaintiff is informed and believes and based thereon alleges that, when the above representations and/or omissions were made by Defendants, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Defendants with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing surgeons and hospitals to use and recommend the off-label use of Infuse.

344. Plaintiff is informed and believes and based thereon alleges that, at the time the aforesaid representations and/or omissions were made by Defendants, Plaintiff and her medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon Defendants' assertions, promulgated through aggressive sales tactics as set forth herein, that the off-label use of Infuse was safe and effective when, in fact, it was neither.

345. Plaintiff is informed and believes and based thereon alleges that, in direct and indirect reliance upon said representations and/or omissions, Plaintiffs physicians used Infuse in an off-label fusion procedure.

346. Had Plaintiff's physicians been made aware of the inefficacy and serious risks associated with such use, she would not have used it.

347. Had Plaintiff known of the actual dangers of and inefficacy of the off-label use of Infuse, she would not have consented to its use in her surgery.

348. Plaintiff is informed and believes and based thereon alleges that Defendants' motive in failing to advise surgeons and the medical community of these risks and inefficacies was for financial gain and fear that, if it provided proper and adequate information, Infuse would lose sales and market share.

349. Plaintiff is informed and believes and based thereon alleges that, at all times herein mentioned, the actions of Defendants, its agents, servants, and/or employees was wanton,

grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiff in particular, and to the public generally, in that Defendants did willfully and knowingly promote the off-label use of Infuse with the specific knowledge that it would be used by surgeons without adequate instructions and without adequate knowledge regarding its efficacy, risks and side effects.

350. Despite its specific knowledge regarding risks as set forth above, Defendants deliberately recommended the off-label use of Infuse and promoted it as being safe and effective.

351. Plaintiff is informed and believes and based thereon alleges that, at all times relevant herein, Defendants' conduct was malicious, fraudulent, and oppressive toward Plaintiff in particular and the public generally, and Defendants conducted itself in a willful, wanton, and reckless manner by actively violating federal regulations.

352. In doing the things aforementioned, Defendants are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

SIXTH CAUSE OF ACTION -- INTENTIONAL MISREPRESENTATION

(Against All Defendants And Does 1-100)

353. Plaintiffs repeat, reallege, and incorporate herein by this reference, all of the preceding allegations as though set forth in full.

354. In connection with the marketing and sales of Infuse, Defendants made misrepresentations of material facts regarding the merchantability and safety of Infuse for off-label use. As alleged in Applicable FDA Regulations Paragraphs 14 through 20, Defendants reported findings with significantly less incidences of complications than were reported in the data supporting the findings and misrepresented the independence of the authors of the reports on Infuse's off-label use.

355. Had Medtronic Defendants complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate

government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action

356. All of the Defendant Medtronic Managers have been paid sham "consulting fees" in 2006. None of these Defendant Medtronic Managers performed bona fide consulting services for Medtronic. All of these payments constitute kickbacks for purchases made or effected by each physician and/or for the agreement to perform unlawful promotional activities for on-label and off-label sales of Medtronic products.

357. As reported by the United States Senate Committee on Finance, there were several Medtronic employees/agents who provided inaccurate or misleading information. Dr. John Kenneth Burkus, a Medtronic consultant, admitted via email that he expected a Medtronic study to be endorsed by authors who did not author the article. Julie Bearcraft, a Medtronic employee, asked that reports of adverse events associated with Infuse Bone Graft be omitted. Rick Treharne, a Medtronic employee, admitted via email that he helped author a spinal surgery study, even though he is not a medical doctor. Bill Martin, a Medtronic employee, stated via email that off-label surgeries should not be discouraged.

358. In agreeing to undergo a procedure whereby Infuse Bone Graft was implanted, Plaintiff justifiably relied on such misrepresentations by Medtronic Defendants, the referenced Medtronic employees/agents and specifically the Medtronic sales representative who was present in Plaintiffs' operating room and orchestrated Plaintiffs' surgery.

359. In agreeing to undergo a procedure whereby Infuse was implanted, Plaintiff justifiably relied on such misrepresentations by Defendants.

360. Said reliance on the misrepresentations has caused, now causes, and will continue to cause significant physical harm, discomfort, damages, and injuries to Plaintiff as alleged and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

SEVENTH CAUSE OF ACTION -- CALIFORNIA UNFAIR COMPETITION LAW

(Bus. & Prof. Code § 17200 et seq.)

(Against All Defendants And Does 1-100)

361. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

362. Under California Unfair Competition Law ("UCL"), Business & Professions Code § 17200, et seq., Defendants owed a duty to Plaintiffs not to provide unfair, deceptive, untrue, or misleading advertising related to the safety and efficiency of its Infuse drug and a duty not to commit unlawful, fraudulent, or unfair business acts or practices.

363. Defendants violated this duty and committed unfair business acts under the UCL by proactively marketing Infuse for off-label usage, including with spinal fusion surgery in violation of FDCA regulations and Infuse's Premarket Approval. In addition, Defendants violated its duty and committed unfair business acts under the UCL by misrepresenting to Plaintiffs' physician the risks associated with such usage. As a direct and proximate consequence of Defendant's acts, omissions, and misrepresentations as described herein and Plaintiffs' physicians' reliance on the same, Plaintiffs were harmed.

364. Plaintiffs are informed and believe that Defendants' conduct is not just limited to its marketing to Plaintiffs' physician and Plaintiffs, but rather is part of a design, pattern, practice, and business practice designed to injure and/or mislead and/or defraud customers, including Plaintiffs' physician and Plaintiffs, to purchase and use its Infuse drug.

365. Plaintiffs are informed and believe that Defendants' conduct and acts of unfair competition are ongoing and present a continuing threat of harm to the general public.

366. Plaintiffs are informed and believe that Defendants have profited by means of its wrongful conduct. This profit amounts to "ill-gotten gain."

367. Plaintiffs are informed and believe that Defendants had specific knowledge of the unusually high rate of off-label Infuse use, that the drugs were not manufactured, tested, or validated in accordance with the FDCA and Infuse's Premarket Approval and that the drugs were adulterated when they left Defendant's control.

368. Defendants' conduct, as set forth herein, was done with oppression, fraud, and/or malice, and in conscious, willful, and reckless disregard of Plaintiffs' health, safety, and welfare.

Accordingly, Plaintiffs are to recover exemplary and punitive damages and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

EIGHTH CAUSE OF ACTION -- BREACH OF EXPRESS AND IMPLIED WARRANTIES

(Against All Defendants And Does 1-100)

369. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

370. At all times herein mentioned, Defendants utilized journal articles, advertising media, sales representatives and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of the Infuse Bone Graft and expressly and impliedly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in posterior procedures was safe and effective.

371. Defendants knew or, in the exercise of reasonable diligence, should have known that such off-label uses had the serious side effects set forth herein.

372. Plaintiffs are informed and believes and based thereon alleges that Plaintiffs' treating surgeons, doctors, and other physicians and medical professionals, relied on Defendants' express and implied warranty representations regarding the safety and efficacy of off-label use of Infuse Bone Graft, but such off-label uses, was not effective, safe, and proper for the use as warranted in that such it failed, migrated, lead to unwanted bone growth and was dangerous when put to its promoted use.

373. Plaintiffs are informed and believe and based thereon allege that Defendants breached the implied warranties of merchantability and fitness because the Infuse Bone Graft is unsafe for the promoted uses, is not merchantable, is unfit for its promoted use when sold, is unfit for the purpose for which it was sold, and/or is not adequately packaged and labeled, and did not reasonably conform to the promises or affirmations of fact made by Defendants.

NINTH CAUSE OF ACTION -- NEGLIGENCE PER SE

(Against All Defendants And Does 1-100)

374. Plaintiffs repeat and reallege every allegation set forth above as if fully set forth herein.

375. Defendants violated applicable federal statutes and regulations relating to medical devices.

376. Defendants' violations of these federal statutes and regulations caused Plaintiffs' injuries.

377. Plaintiffs' injuries resulted from an occurrence in which the federal statutes and regulations were designed to prevent.

378. Had Medtronic Defendants complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action

379. Plaintiffs are of the class of persons whom these federal statutes and regulations were meant to protect.

380. Defendants' violations of these statutes and regulations constitute negligence per se.

381. As a proximate result of the concealment or suppression of the material facts, Plaintiffs sustained injuries and damages alleged herein and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

TENTH CAUSE OF ACTION -- STRICT LIABILITY

(Against All Defendants And Does 1-100)

382. Plaintiffs repeat and reallege every allegation set forth above, as if they fully set forth herein.

383. At all times herein mentioned, Defendants placed Infuse on the market

384. At all times herein mentioned, the off-label use of Infuse in a cervical or lumbar fusion procedure was defective, unsafe, and ineffective, and Defendants knew or should have

known that it was unsafe and ineffective when used in an off-label manner as promoted, instructed and supplied by Defendants, and as utilized in Plaintiffs' surgery.

385. Had Medtronic Defendants complied with their duties to the FDA and as described under the FDCA, the necessary and resultant actions by the FDA and/or appropriate government agencies, would have precluded the use of the product in the surgery giving rise to all causes of action.

386. At all times herein mentioned, Defendants had specific knowledge of the risks involved in the off-label use of Infuse when used in surgery.

387. At all times herein mentioned, Plaintiff relied upon the misrepresentations of Defendants, in and utilized the product in an off-label manner as promoted and instructed by Defendants.

388. At all times herein mentioned, the off-label use of Infuse produced serious side effects, including unwanted bone growth and migration, and Defendants knew or should have known that said usage could be unsafe because of said side effects.

389. Plaintiff was given Infuse in a manner that had been illegally promoted and intended by Defendants.

390. Defendants promoted the off-label use of Infuse with the knowledge of its risk to patients.

391. The off-label use of Infuse, as given to Plaintiff was ineffective, defective, and dangerous when manufactured, designed, promoted, and instructed by Defendants, who is strictly liable for the injuries arising from its use.

392. The risks attendant to the off-label use of Infuse greatly outweighed the benefits to be expected from said use as promoted by Defendants.

393. The off-label use of Infuse failed to perform in a manner that a reasonable consumer would expect it to perform.

394. Plaintiffs are informed and believe, and thereon allege, that Defendants knew that Infuse, when used off-label in the manner described above and as promoted and instructed by

Defendants, was defective and dangerous in the manner hereinbefore described; that Defendants knew that, because said use was dangerous and defective when so used off-label, the product could not be safely used for the purpose intended; that Defendants, knowing that said product when used off-label was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Plaintiffs' safety, when it placed the product on the market without warning of the defect, and knew when so placed that it would be used without inspection for defect when so used.

395. By placing said product on the market and promoting said off-label use, Defendants impliedly represented it was safe for the purpose intended, and intended that doctors and patients in the general public should rely on their misrepresentations. Plaintiff and her doctors did rely on each of said misrepresentations, all to their damage as hereinabove alleged. In doing the things aforementioned, Defendants are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

ELEVENTH CAUSE OF ACTION

Punitive Damages

396. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

397. At all times herein referenced, officers, directors, and managing agents of MEDTRONIC knew, and were aware, and concealed, hid, and/or otherwise downplayed the true risks of non-FDA approved off-label uses of its product INFUSE™

398. At all times herein referenced, officers, directors, and managing agents of MEDTRONIC knew, and were aware, that numerous people had ectopic bone formation, radiculitis, osteolysis, cage migration, and worse overall outcomes as a result of non-FDA approved off-label uses of its product INFUSE™.

399. The MEDTRONIC defendants designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled,

advertised, promoted, marketed, supplied, distributed, wholesaled, and sold INFUSE™, a product which said Defendants knew to be dangerous and unsafe for the purpose for which they intended it to be used, namely, as a bio-engineering bone draft device in spinal fusion surgeries.

400. At all times herein mentioned, prior to and at the time that the MEDTRONIC Defendants design, manufactured, promoted, marketed, supplied, distributed, and/or sold INFUSE™ to Plaintiff, and prior to the time that said product was used, the MEDTRONIC Defendants knew, or should have known, that INFUSE™ was defectively designed and manufactured, that it had extremely dangerous properties and defects, and that it had defects which would cause serious injuries and damage to users of said product, thereby threatening the life and health of the users. Further, at all times, the MEDTRONIC Defendants knew that INFUSE™ had caused serious injuries and damage to other members of the public.

401. At all times herein mentioned, the MEDTRONIC Defendants, despite the actual knowledge described hereinabove, intentionally suppressed the aforementioned complaints, actively concealed and downplayed the risks associated with INFUSE™, actively promoted the illegal, off-label use of INFUSE™, failed to warn Plaintiffs and the medical community of the true risks associated with INFUSE™, and saturated the scientific and medical literature with biased, industry-funded studies to conceal the true risks of INFUSE™, and otherwise failed to warn Plaintiff, the medical community, and/or the general public.

402. At all times herein mentioned, the MEDTRONIC Defendants had actual knowledge of the facts hereinabove alleged demonstrating that serious injury to patients in which INFUSE™ was implanted, particularly in an off-label manner such as the fusion surgery Plaintiffs underwent. The MEDTRONIC Defendants nevertheless deliberately suppressed, concealed, downplayed, and/or otherwise hid any information demonstrating the true risks associated with INFUSE™ from Plaintiffs, the medical community, and/or the general public. Instead, the MEDTRONIC Defendants continued to actively promote the illegal, off-label use of INFUSE™ to spine surgeons in an effort to maintain INFUSE™'s enormous profitability.

403. As a legal and proximate result of the MEDTRONIC Defendants' conduct, as herein alleged, Plaintiffs sustained the injuries and damages set forth above.

404. The MEDTRONIC Defendants' conduct and omissions, as set forth above, in allowing such an extremely dangerous product to be used by members of the general public, including Plaintiffs, constitutes fraud, malice and oppression toward Plaintiffs and others, and a conscious disregard of the safety of Plaintiffs and others.

405. Plaintiffs are therefore entitled to exemplary or punitive damages, which would serve to punish the Defendants and to deter wrongful conduct in the future.

406. Plaintiffs are therefore entitled to judgment against the MEDTRONIC Defendants as hereinafter set forth

DEMAND FOR JURY TRIAL

407. Plaintiffs hereby demand a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

408. For general damages in a sum exceeding this Court's jurisdictional minimum;

409. For specific damages according to proof;

410. For economic and non-economic damages in a sum exceeding this Court's jurisdictional minimum;

411. For punitive and exemplary damages according to proof;

412. For pre-judgment interest and post-judgment interest as allowed by law;

413. For the costs of suit herein incurred; and

414. For medical and related expenses according to proof;

415. For loss of earnings according to proof;

416. For exemplary and punitive damages according to proof;

417. For cost of suit herein;

418. For injunctive relief, enjoining Defendants from the acts of unfair competition and untrue and misleading advertising;

419. For a disgorgement of profits, according to proof; and

420. For such other and further relief as the Court may deem just and proper, including prejudgment interest.

Respectfully submitted,

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